UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2022

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from_____ to

Commission file number: 001-39949

Hyperfine, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**98-1569027**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

351 New Whitfield Street
Guilford, Connecticut 06437
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (866) 796-6767

Securities registered pursuant to Section 12(b) of the Exchange 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**

Securities registered pursuant to Section 12(g) of the Exchange Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		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. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of the registrant's voting and non-voting common equity held by non-affiliates of the registrant (without admitting that any person whose shares are not included in such calculation is an affiliate) computed by reference to the price at which the common equity was last sold as of the last business day of the registrant's most recently completed second fiscal quarter was approximately $120.5 million.

As of March 1, 2023, the registrant had 55,991,074 shares of Class A common stock outstanding and 15,055,288 shares of Class B common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

The following documents (or parts thereof) are incorporated by reference into the following parts of this Form 10-K:

Certain information required in Part III of this Annual Report on Form 10-K is incorporated by reference from the Registrant's Proxy Statement for the 2023 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission.

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CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), that relate to future events or our future financial performance regarding, among other things, the plans, strategies and prospects, both business and financial, of the Company. These statements are based on the beliefs and assumptions of our management team. Although we believe that our plans, intentions and expectations reflected in or suggested by these forward-looking statements are reasonable, we cannot assure you that we will achieve or realize these plans, intentions or expectations. Forward-looking statements are inherently subject to risks, uncertainties and assumptions. Generally, statements that are not historical facts, including statements concerning possible or assumed future actions, business strategies, events or results of operations, are forward-looking statements. These statements may be preceded by, followed by or include the words "believes," "estimates," "expects," "projects," "forecasts," "may," "will," "should," "seeks," "plans," "scheduled," "anticipates" or "intends" or similar expressions. Forward-looking statements contained in this Annual Report on Form 10-K include, but are not limited to, statements about:

- the success, cost and timing of our product development activities;
- the commercialization and adoption of our existing products and the success of our future product offerings;
- the potential attributes and benefits of our products and services;
- our ability to obtain and maintain regulatory approval for our products, and any related restrictions and limitations of any approved product;
- our ability to identify, in-license or acquire additional technology;
- our ability to maintain our existing licensing, manufacturing and supply agreements;
- our ability to compete with other companies currently marketing or engaged in the development of magnetic resonance imaging technologies, many of which have greater financial and marketing resources than us;
- the size and growth potential of the markets for our products and services, and the ability of our products and services to serve those markets, either alone or in partnership with others;
- the pricing of our products and services and reimbursement for medical procedures conducted using our products and services;
- changes in applicable laws or regulations;
- our estimates regarding expenses, revenue, capital requirements and needs for additional financing;
- our ability to raise financing in the future;
- our financial performance;
- our success in retaining or recruiting, or changes required in, our officers, key employees or directors;
- intense competition and competitive pressures from other companies in the industry in which we operate;
- the anticipated benefits of the Business Combination;
- market conditions and global and economic factors, such as inflation;
- our intellectual property rights;

- the effect of legal, tax and regulatory changes; and
- the impact of the COVID-19 pandemic on our business and operations.

These and other factors that could cause actual results to differ from those implied by the forward-looking statements in this Annual Report on Form 10-K are more fully described in Item 1A under the heading “Risk Factors.” The risks described under the heading “Risk Factors” are not exhaustive. Other sections of this Annual Report on Form 10-K, such as the description of our Business set forth in Item 1 and our Management’s Discussion and Analysis of Financial Condition and Results of Operations set forth in Item 7 describe additional factors that could adversely affect our business, financial condition or results of operations. New risk factors emerge from time to time, and it is not possible to predict all such risk factors, nor can we assess the impact of all such risk factors on our business or the extent to which any factor or combination of factors may cause actual results to differ materially from those contained in any forward-looking statements. Forward-looking statements are not guarantees of performance. You should not put undue reliance on these statements, which speak only as of the date hereof. All forward-looking statements attributable to the Company or persons acting on the Company’s behalf are expressly qualified in their entirety by the foregoing cautionary statements. We undertake no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

SUMMARY OF RISK FACTORS

Our business is subject to numerous risks and uncertainties that you should consider before investing in our securities. Some of the principal risk factors are summarized below:

- We are an early-stage life sciences technology company with a history of net losses, which we expect to continue, and we may not be able to generate meaningful revenues or achieve and sustain profitability in the future.
- We have a limited operating history, which may make it difficult to evaluate the prospects for our future viability and predict our future performance. As such, you cannot rely upon our historical operating performance to make an investment or voting decision regarding us.
- We may need to raise additional capital to fund commercialization plans for our products, including manufacturing, sales and marketing activities, expand our investments in research and development, and commercialize new products and applications.
- Our success depends upon market acceptance of our products and services, our ability to develop and commercialize existing and new products and services and generate revenues, and our ability to identify new markets for our technology.
- We are undertaking internal restructuring activities that could result in disruptions to our business or otherwise materially harm our results of operations or financial condition.
- Medical device development is costly and involves continual technological change, which may render our current or future products obsolete.
- We will be dependent upon the success of our sales and customer acquisition and retention strategies.
- If we do not successfully manage the commercialization of our products and services, including continuing to build our sales force, and the development and launch of new products and services, we will not meet the long term forecasts and our business, operating and financial results and condition could be adversely affected.
- If we are unable to attract, recruit, train, retain, motivate and integrate key personnel and expand our organization, our operations may be disrupted, and we may not achieve our goals.
- We have limited experience in marketing and selling our products and related services, and if we are unable to successfully commercialize our products and related services, our business and operating results will be adversely affected.
- We rely on a single contract manufacturer, Benchmark Electronics, Inc. (“Benchmark”), to test, assemble and supply our finished products. If Benchmark fails to fulfill its obligations under its existing contractual arrangements with us or does not perform satisfactorily, our ability to source our devices could be negatively and adversely affected.
- We rely on a limited number of suppliers for our products. A loss of any of these suppliers could negatively affect our business.
- Pricing pressures from contract suppliers or manufacturers on which we rely may impose pricing pressures.
- If we do not successfully optimize and operate our sales and potential future distribution channels or we do not effectively expand and update our infrastructure, our operating results and customer experience may be negatively impacted.
- The market for our products and services is new, rapidly evolving, and increasingly competitive, as the healthcare industry in the United States is undergoing significant structural change, which makes it difficult to forecast demand for our products and services.
- As international expansion of our business occurs, it will expose us to market, regulatory, political, operational, financial and economic risks associated with doing business outside of the United States.
- The COVID-19 pandemic has and could continue to negatively affect various aspects of our business, make it more difficult for us to meet our obligations to our customers, and result in reduced demand for our products and services, which could have a material adverse effect on our business, financial condition, results of operations, or cash flows.
- Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.

- We are subject to extensive government regulation, which could restrict the development, marketing, sale and distribution of our products and could cause us to incur significant costs.
- There is no guarantee that the FDA will grant 510(k) clearance or premarket approval of our future products, and failure to obtain necessary clearances or approvals for our future products would adversely affect our ability to grow our business.
- If we fail to obtain regulatory authorizations in other countries for existing products or products under development, we will not be able to commercialize these products in those countries.
- We may be subject to enforcement action if we engage in improper or off-label marketing or promotion of our commercial medical device products, including fines, penalties and injunctions.
- Because we do not require extensive training for users of our current products, although they are limited under the FDA's marketing clearances to use by, and that images generated from the scanner be interpreted by, trained healthcare practitioners, there exists a potential for misuse of these products, misinterpretation of images by untrained professionals or misuse of these products by untrained professionals, which could ultimately harm our reputation and business.
- We are subject to complex and evolving U.S. and foreign laws and regulations regarding privacy, data protection, and other matters. Many of these laws and regulations are subject to change and uncertain interpretation, and could result in claims, changes to our business practices, monetary penalties, increased cost of operations, or declines in customer growth or engagement, or otherwise harm our business.
- Cybersecurity risks and cyber incidents could result in the compromise of confidential data or critical data systems and give rise to potential harm to customers, remediation and other expenses, expose us to liability under federal or state law, consumer protection laws, or other common law theories, subject us to litigation and federal and state governmental inquiries, damage our reputation, and otherwise be disruptive to our business and operations.
- If we are unable to obtain and maintain and enforce sufficient intellectual property protection for our products and technology, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our products may be impaired.
- We currently rely on licenses from third parties, and in the future may rely on additional licenses from other third parties, and if we lose any of these licenses, then we may be subjected to future litigation.
- We face the risk of product liability claims and may be subject to damages, fines, penalties and injunctions, among other things.
- We identified material weaknesses in our internal control over financial reporting. If our remediation measures are ineffective, or if we experience additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls in the future, we may not be able to report our financial condition or results of operations accurately or in a timely manner and we may be unable to maintain compliance with applicable stock exchange listing requirements, which may adversely affect investor confidence in us and, as a result, materially and adversely affect our business and the value of our Class A common stock.
- Because we are a "controlled company" within the meaning of the Nasdaq listing rules, our stockholders may not have certain corporate governance protections that are available to stockholders of companies that are not controlled companies.
- The dual class structure of our common stock has the effect of concentrating voting power with Jonathan M. Rothberg, Ph.D., Vice Chairperson of our board of directors and the Founder of Legacy Hyperfine and Liminal, which will limit an investor's ability to influence the outcome of important transactions, including a change in control.

These and other material risks we face are described more fully in Item 1A, Risk Factors, which investors should carefully review prior to making an investment decision with respect to the Company or its securities.

PART I

All brand names or trademarks appearing in this report are the property of their respective holders. Use or display by us of other parties' trademarks, trade dress, or products in this report is not intended to, and does not, imply a relationship with, or endorsements or sponsorship of, us by the trademark or trade dress owners. Unless the context requires otherwise, references in this report to the "Company," "we," "us," and "our" refer to Hyperfine, Inc. and its wholly-owned subsidiaries, including Hyperfine Operations, Inc., or Legacy Hyperfine, and Liminal Sciences, Inc., or Liminal, as the case may be.

Item 1. BUSINESS

Overview

We are an innovative digital health business with a mission to provide affordable and accessible imaging and monitoring through magnetic resonance imaging ("MRI") to revolutionize healthcare for people around the world. Our Swoop® Portable Magnetic Resonance ("MR") Imaging® System ("Swoop® system") produces high-quality images at a lower magnetic field strength than conventional MRI scanners. Healthcare professionals can use the Swoop® system to make effective clinical diagnoses on a patient in various settings where MRI devices have previously been inaccessible. The easy-to-use interface and portable design of our Swoop® system make it accessible anywhere in a hospital, clinic, or patient care site. We are working to realize our vision of providing affordable and accessible imaging of health conditions worldwide.

MRI is a medical imaging technique used in radiology to image the human body's anatomy and physiological processes. MRI is typically used in various clinical settings for medical diagnosis, the staging of disease, and follow-up treatment. Unlike X-ray computed tomography ("CT") or positron emission tomography ("PET"), MRI does not expose patients to harmful ionizing radiation. We believe MRI offers unrivaled clarity in assessing central nervous system ("CNS"), musculoskeletal, and other diseases and injuries, including brain disorders and injuries.

Despite its advantages, many healthcare institutions worldwide lack the facilities, qualified operators, and capital necessary to acquire and maintain expensive MRI devices. For healthcare institutions with conventional MRI scanners, disadvantages of conventional MRI scanners include their high cost and facility requirements for a specialized MRI suite, as well as the scheduling delays, impact on personnel resources, and risk of adverse events that result from the need to transport critically ill patients to the MRI suite. The Swoop® system is intended for use at the patient's bedside in any professional healthcare facility, such as a physician's office or a critical care facility. The demand for MRI has been augmented by the aging population and the rising prevalence of cancer and cardiovascular, neurologic, and orthopedic conditions. Healthcare professionals and insurers recognize imaging as a cost-effective and non-invasive diagnostic tool for evaluation and ongoing monitoring. The Swoop® system is the next generation of these devices designed to drive costs down and expand the current $28 billion imaging market.

We believe the adoption of the Swoop® system by healthcare professionals has benefits across healthcare communities both in high- and low-resource settings. Our technology allows us to provide decision support and rapid feedback for diagnostic insight for clinicians of various levels of expertise. Through our collaborations with the healthcare community, we have begun to optimize our software ecosystem to harness artificial intelligence ("AI") and cloud technology to transform the system into a bedside clinical decision support platform. These efforts seek to improve image quality, help users analyze images, and reduce the time to diagnosis.

Legacy Hyperfine received initial 510(k) clearance from the U.S. Food and Drug Administration ("FDA") in 2020. The Swoop® system has since been authorized for brain imaging in several countries, including the European Union (CE marking), the United Kingdom (UK Conformity Assessment ("UKCA")), Canada, Australia, New Zealand and Pakistan.
The Swoop® system is 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. We are building our direct commercial infrastructure in the United States and plan to sell our products in other countries through direct sales or distributors. Furthermore, we possess a portfolio of 142 issued patents worldwide and 108 patents pending as of February 15, 2023.

Our wholly-owned subsidiaries, Legacy Hyperfine and Liminal were founded in 2014 and 2018, respectively, by Dr. Jonathan Rothberg, a serial entrepreneur who received the Presidential Medal of Technology and Innovation in 2016 for inventing a novel next-generation DNA sequencing method and has founded more than ten healthcare and technology companies, including 454 Life Sciences, Ion Torrent, CuraGen, Butterfly Network, and Quantum-Si. Legacy Hyperfine has raised over $160 million in equity investments and partnership milestones from leading institutional investors, including GV (formerly Google Ventures), and grants, including the Bill & Melinda Gates Foundation (the "BMGF").

Our Competitive Strengths

We believe that our competitive strengths include the following:

- **There is a large and growing MRI market, and we have the potential to augment conventional MRI capacity and benefit patients around the world.** We believe our solution addresses a vast unmet need across the global market by expanding accessibility to MRI and augmenting the existing capacity of conventional high-field MRI scanners as imaging rates continue to increase across the population and the need for efficient utilization of MRI scanners increases. Our solution is designed to complement conventional MRI scanners currently used in the market, as it seamlessly integrates into relevant hospital systems. Our system is designed to allow users to upload images directly onto hospital systems, such as the picture archiving and communication system ("PACS"), or directly onto our cloud PACS, which then makes images available for diagnostic purposes.

  We believe the Swoop® system can expand the existing $28 billion global imaging market (expected to grow at a 4.9% CAGR from 2022 to 2030) by making MRI available to a more extensive set of patients in both developed and emerging markets, as well as improve the utilization of conventional MRI scanners through decreased wait times and facilitation of patient flow. Our primary focus is to expand the availability of MRI globally and across the care continuum, particularly to patients in intensive care units and emergency departments, where timeliness is critical. An MRI scan can be essential for diagnosis and urgent intervention. The Swoop® system can be wheeled directly to a patient's bedside and offers a prompt solution for those patients who require an MRI scan but are too critically ill to be transported for a conventional MRI scanner and who may otherwise be forced to forego a scan or wait until their condition stabilizes.

  We have also initiated a global research program supported by grant funding from the BMGF to assess the clinical feasibility of our Swoop® system in providing immediate point-of-care brain imaging to infants between the ages of 0 to 24 months in low to medium income countries. We were awarded a $1.6 million grant from the BMGF for providing and equipping twenty sites with our Swoop® system to enable the performance of a multi-site study focused on optimizing diagnostic image quality (the "Project"). During the third quarter of 2021, we were awarded an additional $3.3 million grant, of which $2.5 million was received from the BMGF in September 2021, with the remainder received in April 2022. Both of these grants are designed to support the deployment of a total of 25 Swoop® systems and other services to investigators, which commenced in the spring of 2021 and is expected to fund the program for approximately two years. The ongoing investigation is designed to provide data to validate the use of our Swoop® system in measuring the impact of maternal anemia, malnutrition, infection, and birth-related injury. At December 31, 2022, 20 Swoop® system units and 10 baby cradles were provisioned and delivered to BMGF and the majority of the milestones for service deliverables were also met.

The Swoop® system is designed to create value for stakeholders across the care continuum:

- **Our innovative technology can potentially improve the quality of care for patients worldwide.** We believe our smaller, portable, affordable, effective MRI scanner can broaden access to quality care, leading to improved health outcomes. In many cases, other imaging modalities, such as computerized tomography ("CT") scanners, are used due to the lack of availability of MRI scanners or their lower cost profile, even though CT provides lower soft tissue contrast for evaluating abnormalities in the brain. Our point-of-care Swoop® system has a significantly lower price point than conventional MRI and CT scanners, making the Swoop® system affordable for hospitals and care centers that are not financially able to acquire a conventional MRI or CT scanner. Compared to CT scans, MRI has a greater range of soft tissue contrast, depicts anatomy in greater detail, and is more sensitive and specific for abnormalities within the brain itself. Our Swoop® system is designed primarily for urgent cases and can also benefit non-urgent cases. Among the neurological conditions for which the Swoop® system can provide a first-line

diagnostic capability, we expect the Swoop® system's top clinical use cases will continue to be point-of-care MRI in acute mental change assessment and follow-up in an ICU setting; stroke workflow; and pediatric and adult point-of-care assessment of hydrocephalus, an abnormal buildup of fluid within the brain.

Our solution can potentially improve the diagnosis and lives of the approximately 15 million annual new stroke sufferers worldwide. The Swoop® system does not emit ionizing radiation and therefore does not have the increased risk of cancer that comes with CT imaging. The absence of ionizing radiation is significant for conditions that require regular follow-up with multiple scans per year, such as hydrocephalus. In certain circumstances, such as in the management of patients with delirium or altered mental status, familiarity or keeping the surrounding environment as similar as possible can be critical, which we believe makes bedside devices like our Swoop® system particularly useful since patients do not need to move to distant radiology suites for conventional MRI scans. Studies show that 37% of patients report anxiety-related reactions in an isolated room for imaging. With our Swoop® system, we can offer a quieter, calmer experience with the option of a family member or other caregiver being present by the patient's bedside during the scanning process.

Our point-of-care Swoop® system also helps avoid the risk of patient injury during transport through the ability to bring the system to the patient. By performing scans for urgent and critically ill patients at the bedside, we can help prevent the adverse incidents that occur with approximately 26–79% of critically ill patient cases during transport. The Swoop® system also obviates the labor-intensive and high-risk process of transporting patients on ventilators or connected to other life-sustaining devices, which can be especially valuable in the staff shortage environment that many healthcare institutions are experiencing.

- **Our proprietary, disruptive, and revolutionary product is designed with healthcare professionals in mind.** We have commercially launched our Swoop® system, a point-of-care MRI device capable of producing diagnostic quality images at a lower magnetic field strength than conventional MRI scanners. Using an ultra-low-field magnetic force significantly reduces projectile safety concerns and, therefore, should reduce the length of pre-safety checks typically conducted by healthcare professionals. We designed our product with the physician workflow in mind, reducing the average 11.7-hour conventional MRI process to 0.5 to 5.3 hours of workflow time with our Swoop® system. Typically with a 55% or greater reduction in total workflow time, physicians can reduce the time to diagnoses for timely treatment, potentially resulting in improved health outcomes for the patient.

  For healthcare professionals already facing demanding time constraints, dealing with lengthy and sometimes confusing MRI protocols adds to their time spent on logistics rather than caring for patients. Additionally, conventional MRI scanners require specially trained technicians fully dedicated to operating those systems and increase the time and cost related to nurses and porters transporting patients to the MRI unit. Our Swoop® system is designed to simplify the image acquisition process. We have designed our system to be user-friendly and require minimal training to be operated. Our platform can be controlled by a tablet, smartphone, or any other Wi-Fi-capable device. The Swoop® system's portability and accessibility at the bedside can further allow more time for healthcare professionals to focus on other important activities related to patient care, diagnosis, and treatment.

- **Our first in its class product provides an attractive return on investment for various care settings.** We created the Swoop® system not to replace conventional MRI devices but to supplement their existing capacity. By enabling imaging at the bedside, patients can be treated earlier and discharged sooner, potentially leading to increased hospital savings consistent with the growing shift to value-based care. In addition, by conducting more in-patient MRI scans at the bedside, our Swoop® system can help free up capacity in the MRI suite for additional outpatient procedures, which generate higher revenues for hospitals or other healthcare facilities than in-patient imaging. In studies we have conducted in hospital settings, the use of our Swoop® system has helped to make capacity available that has resulted in 20% increased usage of the existing MRI suite for additional outpatient procedures.

  As healthcare costs continue to rise, we believe our Swoop® system will allow for significant potential cost reductions that can benefit the entire imaging ecosystem. Our Swoop® system has dramatically reduced hardware costs through design trade-offs, compensating using modern computational power and deep learning advances. The cost benefits of our Swoop® system are not limited to a customer's initial purchase of the system. Our customers continue to benefit by not having to spend on additional cooling, power, and maintenance expenses throughout the lifetime of conventional MRI. Unlike conventional MRI scanners, the use of the Swoop® system also does not require a specialized radio frequency (RF) room to safely house the MRI scanner, allowing space for other essential patient care activities. Using the Swoop® system in the ICU can also increase utilization by allowing critically ill patients to receive immediate access to an MRI instead of adding congestion in the schedule of the conventional MRI scanners due to complications in the patient's condition and unexpected changes in their condition or treatment.

- **Our validated platform and business model allows for potential widespread adoption.** Over 50 conference presentations and publications have discussed the clinical benefits of point of care, low-field MRI for patients with stroke, hydrocephalus, hematoma, multiple sclerosis and tumor resection. We generate sales revenue by selling the Swoop® system primarily through one business model, which is ownership accompanied by an annual service and support agreement. In this model, the Swoop® system is typically sold with a service and support agreement that begins in year one and is sold initially in either 36- or 60-month terms. In certain cases, the Swoop® system is sold without an accompanying service and support agreement. We believe this makes a convenient and positive experience for our customers. As more healthcare professionals adopt our technology, we anticipate improvements in gross margin due to increased volume and the recurring subscription base of the business.
- **We have a strong lean executive leadership team with deep expertise in healthcare.** We have a world-class management team, including our executive officers and other senior management, with decades of cumulative experience in healthcare and consumer end-markets. Our team is comprised of experienced leaders with deep leadership experience in medical device development, manufacturing, and commercialization. We believe our leadership team will drive the company to be a disruptive force in revolutionizing MRI.

Our Strategies

Our strategies include the following:

- **Focus our development and commercialization efforts on the Swoop® system.** In addition to our efforts to develop and commercialize the Swoop® system, we were previously working to develop a non-invasive brain sensing technology that is more affordable, accessible, and safer, to enable healthcare professionals to more easily monitor key brain vital signs such as cerebral blood flow and intracranial pressure throughout patient care. In December 2022, we suspended our program to develop a device to non-invasively measure key vital signs in the brain to focus our resources on the continued development and commercialization of the Swoop® system.
- **Focus on our customers through success programs.** Our Swoop® system is designed to make the customer experience as easy as possible through our integrated, easy-to-use interface that portrays images on a tablet device. In addition to this design, our team is focused on clinical support programs to help integrate the Swoop® system into any hospital or clinic workflow. We believe that the use of our Swoop® system within hospitals will provide us with opportunities to cross-sell our product and services across departments and reduce customer acquisition costs as customers become more accustomed to the use of our Swoop® system across their facilities and observe the improved health outcomes and decreased costs that the use of our Swoop® system may provide. We expect our clinical support programs to increase our customer referral rates across the medical imaging market as our product continues to be validated and supported by healthcare professionals in the field.

  Our clinical support program is designed to ensure that our customers achieve their desired outcomes using our Swoop® system. Our team seeks to foster long term relationships, highlight key product benefits, and manage customer expectations. The program is designed to guide customers to maximize the product's utilization and enhance their experience through ongoing educational tools and opportunities. Our customer success team aims to ensure a smooth path to obtain customer loyalty and continue to grow our install base with subscription renewals, follow-up sales, and new Swoop® system placements.
- **Demonstrate our commitment to continuous technical innovation and leadership across the care continuum.** Our advanced technology in imaging is supported by an internal team of scientists and engineers dedicated to continuous innovation. Our pace of AI-powered software iterations allows further improvements of image quality, consistency, and image sequences for the clinical uses of our technology. As the Swoop® system becomes integrated into ICUs and sites across medical practices, we are dedicated to gaining more insights into our product’s usability and potentially develop the automated analysis of images that we believe will lead to further efficiencies in patient diagnosis. We plan to continue developing our technology to expand into new imaging applications to enable us to reach the broader care continuum through diagnosis and treatment. In the future, we plan to introduce a further enhanced MRI system designed to conduct neuroimaging and imaging of other parts of the human anatomy.
- **Expand clinical validation data and publications.** There are over 50 conference presentations and publications discussing the clinical benefits of our Swoop® system. *The Journal of American Medical Association* (JAMA) published a detailed study conducted at the Yale-New Haven Hospital on how the Swoop® system successfully detected abnormal neuroimaging findings at the bedside of patients in the ICU, demonstrating the capability of ultra-low-field, point-of-care MRI to obtain neuroimaging at the bedside in intensive care settings. We are also partnering with multiple sites, including Massachusetts General Hospital and SUNY Buffalo, for an upcoming study to examine the use of the Swoop system to assess acute ischemic stroke in the emergency department setting.

  The Swoop® system has been used for diagnoses across various neurological pathologies, and we believe that the Swoop® system could ultimately enable a new paradigm in the standard of care for these diseases that could be lifesaving. We believe the early diagnosis of these diseases has cost-saving benefits for multiple stakeholders, including patients, providers, and payors, as it can lead to earlier intervention and treatment and fewer patient visits.

- **Expand sales in international markets.** We intend to continue to increase our sales and distribution capabilities outside of the United States to take advantage of the large international opportunity for our products. The countries in which we have begun commercializing our Swoop® system include the United Kingdom, Canada, Australia, New Zealand and Pakistan. We obtained a Medical Device License issued by Health Canada, UKCA certification in the United Kingdom, CE marking in the EU and regulatory authorization in Australia, New Zealand and Pakistan.

  While we will maintain our commercial focus in the U.S. in 2023, our commitment to the vision of providing affordable and accessible imaging that enables earlier detection and remote management of health conditions worldwide is in part made possible by grant funding from the BMGF. Through our engagement with nonprofit organizations, we deployed the Swoop® system to low-middle resource settings without readily-accessible MRI technology. The multiple grants provided by the BMGF, which commenced funding in the spring of 2020, support the deployment of 45 Swoop® systems to investigators. The ongoing investigation is designed to provide data to validate the potential use of the Swoop® system in measuring the impact of maternal anemia, malnutrition, infection, and birth-related injury.

Industry and Market

MRI is a non-ionizing radiation risk imaging modality widely used by healthcare professionals across various clinical settings for the medical diagnosis of a patient, staging of disease, and continued assessment following treatment. MRI is noninvasive, sometimes eliminates the need for surgical intervention or invasive procedures when used correctly, and offers superior soft tissue contrast resolution compared to other imaging modalities like CT. It is a more sensitive and potentially objective measure of brain tissue and injury. MRI is used to examine CNS, musculoskeletal, and other diseases. The prevalence and incidence rates of these diseases have increased across the globe. According to a United Nations report, up to one billion people, nearly one in six of the world's population, suffer from neurological disorders, including Alzheimer's and Parkinson's disease, stroke, multiple sclerosis, epilepsy, migraine, brain injuries, and neuro infections, with some 6.8 million dying of these disorders each year.

The aging population and rising prevalence of cancer, cardiovascular, neurological, and orthopedic conditions have augmented the demand for MRI. Healthcare professionals and insurers recognize imaging as a cost-effective and non-invasive diagnostic for prevention and ongoing monitoring. The Swoop® system is the next generation of these devices that we believe will drive improved access and efficiency and expand the current $28 billion imaging market. Given the significant patient populations needing diagnostic imaging, we have positioned ourselves in an underpenetrated market with substantial room for growth. We estimate that the global imaging market will increase to a more than $20 billion opportunity across our potential use cases. This estimate includes over 100,000 hospitals and outpatient locations that we believe could serve as installation sites for our system. While the current imaging market is mainly limited to high-resource countries, we believe our system can help make MRI technology more accessible globally, leading to an increase in both MRI penetration rates and the size of the overall market opportunity.

Market needs

Despite MRI's advantages to diagnose and monitor patients through treatment, access to MRI scanners can be problematic. Numerous challenges are associated with the use of conventional MRI devices:

- *High cost*: The average cost of conventional MRI scanners is $1.2 million and could cost as high as $3 million, significantly more than our Swoop® system. In addition, conventional MRI scanners typically are not offered with our affordable subscription-based pricing model.
- *Complex site requirements and upgrades*: Due to the use of strong (1.5−3.0T (Tesla)) magnetic fields in conventional MRI scanners, there are various requirements and restrictions on radiation therapy ("RT") facilities size, location, and ongoing maintenance, including the need to build a specialized radio frequency room to house the MRI scanner safely.
- *Scheduling delays*: A high level of coordination is required between the MRI facility and the ICU to have patients scheduled for a conventional MRI scan. Coordination is further complicated with patients who are unstable in the ICU and require multiple medical procedures in a timely manner.
- *Maintaining a connection to life support equipment*: Patients in the ICU are often connected to life-sustaining devices that complicate the conventional MRI procedure and transportation to and from the conventional MRI scanner.
- *Consumption of valuable personnel resources*: One of the most challenging aspects of transporting a patient is coordinating a specialized team to manage the patient as they move from the ICU to the MRI. Such a team typically includes two to six staff members. Further challenging the situation, if the department is already short-staffed, taking staff away from the ICU to assist in imaging a patient could put other patients at risk. Additionally, each patient transport for imaging complicates the ICU workload, creating time-intensive patient care interruptions that require specialized nurses to remove and reattach life-sustaining equipment.
- Risk of adverse events during transportation: According to Glavis et al., the workflow for imaging an ICU patient with conventional high-field MRI can take as long as 11.7 hours at their hospital, but other hospitals have anecdotally reported up to 24

hours. Additionally, intrahospital transport of patients is associated with numerous cardiovascular and respiratory risks that may limit timely and safe neuroimaging for critically ill patients. And unfortunately, even under the supervision of a well-trained transport team, adverse events may still occur in approximately 26–79% of critically ill patient cases during transport.

Martin et al. reported that ventilator asynchrony was the most frequent adverse event and put patients at a higher risk for pneumothorax, atelectasis, and ventilator-associated pneumonia. Difficulties occur with hardware, challenges with lifts to move the patient, issues with infusion lines, and a lack of battery life for equipment needed to support the patient. In addition to patient impact, there are expenses associated with each adverse event. According to a study by Mello et al., the average hospital-borne cost of an adverse event is $6,255 (adjusted for inflation).

Due to these challenges, the adoption of conventional MRI scanners has been limited across medical settings in the United States and globally, especially in rural locations where many individuals only have access to small clinics. MRI scanners also include additional charges of establishing an MRI suite, patient support areas, machine installation and servicing, software upgrading, and maintenance that burden hospitals and clinics with limited ongoing funding.

There are significant benefits to diagnosing a disease in its early stages, which can reduce the time to treatment and improve the quality of life for those patients. We have taken advantage of technological advances in electronics and computing to develop an MRI device that is not only portable but also uses an ultra-low-field 64mT (0.064T) magnet, which is much lower than the 1.5T or higher field strength of conventional MRI scanners. Our advanced technology allows healthcare professionals to conduct an MRI scan at the patient's bedside in the hospital or any clinical setting to begin early diagnosis, intervention, and ongoing treatment. Many small- and medium-sized hospitals also consider leasing advanced MRI scanners to provide MRI imaging services without undertaking the potentially more costly long term commitment of purchasing an MRI scanner. Our Swoop® system is available to medical facilities in the United States for purchase with multiple payment options.

According to a 2008 report from the World Health Organization, 90% of the world does not have access to MRI, primarily due to socioeconomic factors. Many low-resource countries recognize the benefit of investing in their healthcare infrastructure, and it is expected to cause a spur in growth for the global MRI market. For example, China is one of the fastest-growing markets building its healthcare infrastructure in rural areas. The ability of these countries to build the facilities needed to house these large systems and train highly specialized personnel to operate conventional MRI scanners presents a challenge.

Products and Services

Our Swoop®Portable MR Imaging® System

We designed our Swoop® system to address an unmet need in point-of-care medical imaging through a unique combination of hardware and AI-powered software services. Our hardware is powered using modern computational power and deep learning advances. Our software addresses the traditional ease-of-use and integration challenges often presented by specialized medical technologies. Our system operates from a Wi-Fi-capable tablet and integrates with picture archiving and communication systems ("PACS") to enable fast and confident clinical decision-making.

Features

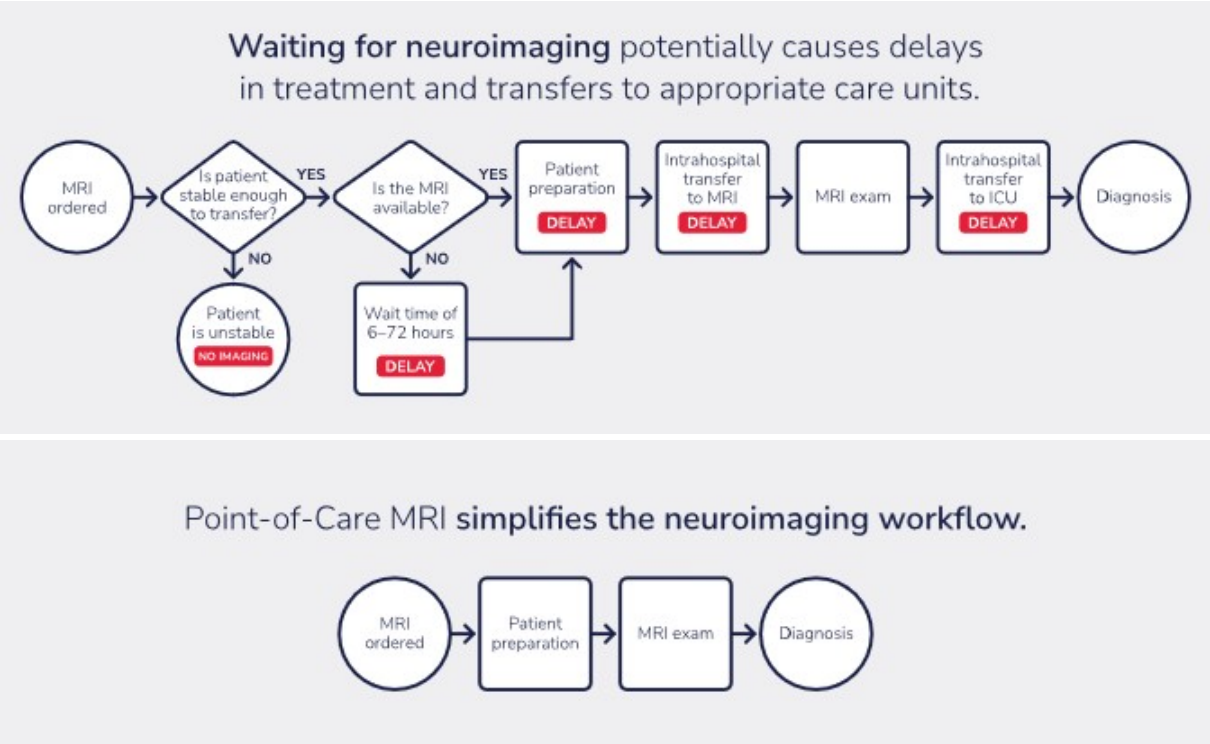
Point-of-Care Neuroimaging—FDA-Cleared for MRI of the Brain and Head in Patients of All Ages

Neuroimaging at the point of care has only been possible using CT. CT can visualize bones or blood vessels well when the patient is injected with a contrast agent but is not as sensitive as MRI at imaging the brain's anatomy. Additionally, CT delivers a significant

amount of ionizing radiation. Exposing patients to radiation increases the risk of developing cancer, which limits CT's use for critically ill patients and makes it particularly hazardous for pediatric patients.

The gold standard for neuroimaging is MRI, which can provide excellent high-resolution images of the soft tissues of the brain without being obscured by the skull. MRI can provide critical insight into brain trauma and disease but historically has not been available at the point of care. Because of their size, weight, and safety issues, conventional MRI scanners were only available in hospitals, major medical centers, and outpatient imaging providers, meaning that patients typically must be transported to the MRI scanner.

We have developed a new category of medical imaging, point-of-care MRI, that is smaller, lighter weight, and lower cost than conventional MRI scanners yet maintains the soft tissue visualization capabilities critical for neuroimaging. Since launching our FDA-cleared portable Swoop® system in 2020, advanced neuroimaging is now available for patients of all ages at the point of care.



Ultra-Low-Field System

To engineer this new category of point-of-care MRI, we made several significant design changes with respect to conventional MRI, particularly the magnetic field strength. Over the past 40 years, the goal for improving conventional MRI scanners has been to attain higher magnetic field strength. In 2017, the FDA cleared the first 7T MRI, after 20 years of development to establish clinical relevance. It was noted that the added field strength allows for better visualization of smaller structures and subtle pathologies that may improve disease diagnosis. We have taken a different approach by developing our Swoop® system to have an ultra-low-field magnet of 0.064T, which enables MRI to become portable because, unlike conventional MRI scanners, the field strength of the magnet in our system does not require a specialized radio frequency room to house the MRI scanner safely. This field strength comes from a unique optimization of the magnet size, weight, field uniformity, and patented design of the permanent magnet structure that provides sufficient image clarity for diagnostic purposes.

There are additional benefits to operating an MRI system with an ultra-low-field magnet. It reduces the risk of iron-containing objects becoming projectile and injuring patients or operators, a typical concern of conventional MRI scanners. Furthermore, the radiofrequency pulses used in conventional MRI are responsible for 55% of the FDA-reported adverse events from MRI, causing skin and internal burns in some patients. Operating at 0.064T means using lower energy radiofrequency pulses and significantly reducing associated safety risks.

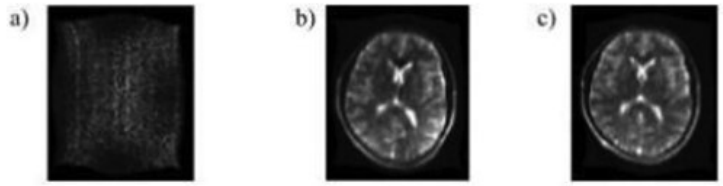
Motion Correction

Portable MRI at the point of care can provide MRI insights to more critically ill patients than previously possible. Conventional MRI scans regularly suffer from quality problems due to patient motion, with approximately 30% of all scans from inpatient or emergency department exams having moderate or severe image quality issues. We have developed motion compensation technology to improve image quality in the most challenging, and often most in need, patients that received FDA clearance for clinical use. We believe that with continued development, our technology can produce diagnostic scans without requiring the operator to make expert adjustments to the scanning procedure due to typical patient movements.

Noise-Cancellation Technology

Designing an ultra-low-field magnet is not sufficient to enable portable MRI. Portable MRI must also address the electromagnetic interference surrounding us. Electromagnetic interference makes conventional MRI outside of a shielded room impossible. Conventional MRI scanners are permanently installed in a special room where the walls, floor, and ceiling are encased in copper or aluminum to provide an environment for conventional MRI machines to operate, in which all man-made and natural electromagnetic interference is prevented from entering. Installation of these shielded rooms typically costs more than $100,000.

We have developed proprietary, patented noise-cancellation technology to enable portable MRI. Our technology measures the external electromagnetic interference and subtracts that from the interference that swamps the MRI signals. The image below shows one slice of an MRI image acquired a) outside a shielded room without noise cancellation, b) outside a shielded room with noise cancellation, and c) inside a shielded room without noise cancellation.



Delivery of Multiple Sequences with Tissue Contrasts

MRI can provide images with different soft tissue contrasts through various sequences that can highlight a range of pathologies. These contrasts are standard in conventional MRI and allow for the differentiation of various tissue types aiding in establishing the diagnosis. Our Swoop® system generates images with contrast weightings with which physicians are most familiar and which are most clinically useful for the target use cases: T1, T2, fluid-attenuated inversion recovery (“FLAIR”), and diffusion-weighted imaging (“DWI”) with apparent diffusion coefficient (“ADC”) maps.

Image Quality

We deliver diagnostic-quality images to healthcare professionals. The images from our Swoop® system are higher in contrast resolution than other portable medical neuroimaging systems, such as portable CT scanners. Our portable Swoop® system also delivers comparable image resolution at 1.5 x 1.5 x 5 mm, 1.6 x 1.6 x 5 mm, or 2.4 x 2.4 x 6mm (depending on the sequence) relative to the typical image resolution of a conventional MRI at 1.0 x 1.0 x 5 mm. Our MRI signal is produced at 0.064T compared to 1.5T or higher produced by conventional, fixed MRI scanners. We believe that the Swoop® system provides the potential to improve the quality of care for patients who have limited or no access to conventional MRI, which includes 90% of the world’s population.

Controlled by an Easy-to-Use Wireless Tablet

As we seek to reach new markets and users with our Swoop® system, we have sought to make the operation of the device as simple and easy to use as possible. We believe it is important to consider usability when significantly changing how a medical device is used, specifically in MRI, where conventionally, the operator is required to have several years of training. We believe this is particularly important when used in emergency situations such as stroke, where time can be critical.

The interfaces to the Swoop® system are simple, intuitive buttons, joystick controls to drive the system, and a familiar tablet controller for image acquisition and viewing. The user interface provided on the touch-screen display offers a playlist of protocols based on the use case that can be started, stopped, and rearranged as needed. In addition to being easy to use and the consequential acceleration of hospital workflows that can result, our system provides standardized images across all placement sites due to our uniform manufacturing specifications and a consistent set of sequences that individual operators do not customize. Conventional MRI scanners are sequenced by highly-trained technologists and can have variations in image resolution and contrast weighting across sites due to institutional policies and radiologist preferences. We believe the standardization of images across scanners and sites will

significantly benefit the ability of radiologists and other healthcare professionals to read our images efficiently and ultimately build a repository of homogenized image data from which to extract value using data mining and deep learning.

Integration with Picture Archiving and Communication System (PACS) and Secure Image Upload to the Cloud

Similar to other medical devices in hospitals, we designed our Swoop® system to seamlessly integrate with the hospital informational technology ("IT") infrastructure, such that scans can be ordered easily and sent to PACS to be read by a radiologist. For applications where access to such infrastructure is unavailable, we also offer a secure cloud based PACS where healthcare professionals, including teleradiology service providers, can view images from anywhere in the world. We believe the combination of portable MRI, where scans can be obtained outside the conventional MRI suite, and teleradiology can significantly improve patient care and increase access.

Fully Automated MRI Post-Processing Software

We believe that bringing the AI's power to MRI has the potential to significantly improve the efficiency of medical imaging in a wide array of use cases, which can benefit the patient by potentially helping to improve outcomes and result in shorter hospital stays. We received FDA clearance for BrainInsight™, our first AI application, in January 2021. BrainInsight™ offers automatic labeling, spatial measurements, and volumetric quantification that operate on images from our Swoop® system and automatically adds these insights and associates them to the images in the PACS. Using this approach, we intend to grow our portfolio of applications with internal and external development and leverage the uniquely standardized (and fully anonymized) record of image data we plan to create with our portable Swoop® system.

Design

Location Flexibility

Despite the weight of our Swoop® system being 1,400 pounds, its powered drive system means operators can move the system around the hospital with minimal effort. The Swoop® system can be moved from bed-to-bed and easily positioned in tight spaces because it turns on the spot with a zero-turn radius.

Open Layout Designed to Potentially Reduce Patient Anxiety

For an MRI scan in a traditional setting, a patient arrives at the radiology department of a hospital and typically enters through a door covered with radiation warnings and other hazard symbols. The patient then proceeds to a waiting room where they undergo a lengthy safety questionnaire and are asked to remove all jewelry and clothes (to their underwear) and put on a hospital gown. Wait times vary from a half hour to several hours before the patient enters the console room and is led through a large metal door into the RF screen room by themselves. Typical conventional MRI scanners are long tubes where the patient is positioned on a motorized bed, and RF coils are attached around the patient who has been instructed to lay still. The MRI technician uses the motorized bed to push the patient into the long tube of the large superconducting magnet, leaves the room, closes the metal door to the scan room, and tells the patient over an intercom that the scan is about to start. The patient hears the steady mechanical thumping of the cryocooler in the magnet room until the scanning starts, accompanied by extremely loud acoustic noises. The conventional MRI procedure is often a daunting experience for the patient that can cause significant anxiety, especially for pediatric patients who are separated from their families during this time.

Unlike conventional MRI, our Swoop® system is entirely contained in a system that is just 55 inches tall and 34 inches wide and is designed to scan patients in their beds. Parents, family, or caregivers can be close to the patient as they are scanned, with just their head in the transparent head RF coil. The system is quiet enough to allow constant verbal contact with the patient, which can create a considerably less distressing experience for the patient compared to that of a conventional MRI scanner.

Powered Using a Standard Wall Outlet

Operable throughout any hospital environment, our Swoop® system plugs into a standard wall outlet (100-230 VAC, 50/60 Hz, 15A) and uses less than 900W of electricity. This ability is achieved with low-power electronics, including efficient power supplies and power amplifiers, coupled with a zero-power consumption permanent magnet. Our Swoop® system does not require many of the components of conventional MRI, including the liquid helium used in conventional MRI superconducting magnets or the associated safety and supporting infrastructure, the chilled water-cooling systems for the power electronics and gradient coils, and the room air conditioning needed to extract the heat generated in the separate electronics machine room, or the special 480 V, 3-phase, 200A power supply.

Services

Unlimited Training and Support Resources

Through our subscription model, we offer several services to complement the advanced features of our product. As part of our subscription, we offer user training during the subscription period to make it as easy as possible for healthcare professionals to operate our system. We offer this support primarily as reassurance to our customers, although we are confident our customers will be able to operate our user-friendly device with ease and efficiency; in our experience so far, the user training on the system is generally simple and only requires a few hours.

The Swoop® system subscription includes support and technical assistance with hardware and software issues. A combination of remote and onsite support in collaboration with onsite technical staff solves software issues. In addition to these support services, our subscription includes our Hyperfine Image Viewer, a cloud archive that users can use to upload images for storage purposes. Subscription also grants access to our future software upgrades. Recent upgrades include our FDA-cleared motion correction technology that improves the quality of images in the presence of motion and other potential future upgrades designed to improve the patient workflow and diagnosis.

Our People

Legacy Hyperfine was founded in 2014 by Dr. Jonathan Rothberg. Our mission is to provide affordable and accessible imaging and monitoring through MRI to revolutionize healthcare for people around the world.

As of February 15, 2023, we had 136 employees, all of whom were full-time employees and of whom 17 work in sales, clinical and marketing, 92 work in research, development, manufacturing and operations, and 27 work in general and administrative capacities. As of February 15, 2023, 133 of our employees were located in the United States and 3 were located in the United Kingdom. None of our employees are represented by a labor union or are subject to a collective bargaining agreement.

Dr. Rothberg and our business have been recognized for leadership. Legacy Hyperfine was founded in 2014 by Dr. Jonathan Rothberg, a serial entrepreneur that received the Presidential Medal of Technology and Innovation in 2016 for inventing a novel next generation DNA sequencing method and has founded more than 10 healthcare and technology companies, including 454 Life Sciences, Ion Torrent, CuraGen, Butterfly Network and Quantum-Si.

Information About Our Executive Officers and Directors

The following persons were our executive officers and directors as of March 1, 2023:

Name	**Position**
Executive Officers	
Maria Sainz	President, Chief Executive Officer and Director
Alok Gupta	Chief Financial Officer
Brett Hale	Chief Administrative Officer
Khan Siddiqui, M.D.	Chief Medical Officer and Chief Strategy Officer
Directors	
R. Scott Huennekens	Executive Chairperson of the Board of Directors
Jonathan M. Rothberg, Ph.D.	Vice Chairperson of the Board of Directors
John Dahldorf	Chief Financial Officer, Santa Cruz Nutritionals
Ruth Fattori	Managing Partner, Pecksland Partners Senior Advisor, Boston Consulting Group
Daniel J. Wolterman	Chief Executive Officer, Wolterman Consulting LLC

Environmental, Social and Governance Practices

As we work toward our mission, we are increasingly focused on providing transparency around our environmental, social and governance (“ESG”) practices and identifying risks related thereto. We are committed to human capital management, patient advocacy and community outreach efforts, corporate governance, and implementing environmental sustainability initiatives.

Environmental Stewardship: We recognize the importance of taking measures to reduce our environmental footprint. As we grow our business, we have initiated certain projects to begin tracking our environmental impact, and where feasible, have taken measures

to increase our sustainability efforts. Some of our efforts include our commitment to reduce, reuse or recycle where possible or appropriate and energy efficient projects to lower energy use within our office areas and laboratories.

Human Capital Management: We believe that our people are the reason for our success and we have organized ourselves to maximize productivity and performance. We maintain a high bar for talent and actively work to build diversity within our workforce. Critical to achieving our strategic goals is our ability to build and retain an exceptional team in which each member plays a unique and important role.

We recognize that maintaining an engaged and top-notch workforce and a connection with the communities we serve are critical to our success. Comradery and community are at the core of who we are as a company and are integral facets of our human capital management strategy. We are inspired by each other and the possibilities of what we can achieve together. We understand that in order to drive innovation, we must continuously improve our human capital management strategies and find ways to foster engagement and growth within our organization. To this end, below are some of our initiatives:

Professional Development Programs and Opportunities: Our greatest asset is our employees and we aspire to provide them with opportunities so they can continue to grow and excel in their functions and our company. Professional growth of our employees leads to engagement, development and allows us to leverage opportunities so we can hire and promote key talent from within. Through development planning, we strive for employees at all levels to focus on strengthening the skills required in their current role and potentially their next role. We are focused on building a culture of continuous coaching, feedback and open communication between managers and their direct reports throughout the entire year. We provide managers and employees with training on how to conduct effective forward-looking performance conversations and to set effective goals that are realistic, measurable, attainable, relevant and timebound.

Diversity, Equity and Inclusion: Our commitment to maintaining a top-performing company means investing in and creating ongoing opportunities for employee development in a diverse and inclusive workplace. We believe that a diverse workforce not only positively impacts our performance, fosters innovation, inspires us to achieve greater results, increases our collective capabilities and strengthens our culture, but it also cultivates an essential pipeline of experienced leaders for management. Hiring for diversity of thought, background and experience, and diversity of personal characteristics such as gender, race and ethnicity is intentional and continues to be an area of focus as we build and grow our workforce.

Compensation, Equity and Benefits: We have designed a broad-based compensation program that is designed to attract, retain and motivate our employees to deliver sustainable long term value. We seek to deliver performance-driven, market competitive reward opportunities commensurate with company and individual performance. Many of our employees receive equity grants and cash bonuses in addition to base salaries and our benefits package. We believe that providing employees with an ownership interest in our company further strengthens the level of employee engagement. Furthermore, equity awards help align the interests of our employees with the long term interests of our stockholders. We also offer employees a health insurance package.

Governance, Ethics, and Compliance: Our board of directors is committed to robust corporate governance practices, risk oversight, stockholder rights, diversity, equity and inclusion, corporate sustainability, ethics and compliance in order to protect the long term interests of our company, stockholders and the patients we serve. Our board of directors adopted corporate governance principles applicable to us, including responsible oversight and management of the Company, effective controls and processes, compliance with SEC and Nasdaq Stock Market rules and regulations, maintaining an engaged board of directors and a board structure that recognizes the importance of compliance, diversity, appropriate compensation practices, and succession planning, among other matters.

We will continue to evolve and strengthen our human capital management strategies, increase our environmental efforts, maintain and continue to improve our corporate governance practices, and anticipate reporting on other corporate sustainability measures over time.

Marketing, Sales and Pricing

Marketing

Our marketing efforts are focused on accelerating awareness of our products and capabilities in order to create a strong reputation with clinicians and healthcare administrators. Our go-to-market approach features a targeted sales organization complemented by an array of promotional activities including media coverage, tradeshow exhibition, advertising, and live product demonstration. We principally target ICU, comprehensive and primary stroke accredited facilities. In the future, we plan to leverage this approach for both our Swoop® system and our future products that have similar end markets.

We recognize the role of education in accelerating clinical adoption of our products across the patient care pathway, including healthcare professionals who currently may not themselves be primary users of MRI technology. To support adoption of our product and in addition to our simplified product interface, we are in the process of developing a training curriculum and tutorials and have

built a team of clinically trained clinical support specialists to guide and coach clinicians on the unique features of our device and on the specific clinical application of our technologies.

Sales and Pricing

The Swoop® system is commercially available in the United States, Canada, Australia, New Zealand, Pakistan, and the United Kingdom, and the system also has received CE marking in the European Union. We are building our direct commercial infrastructure in the United States and also sell our products in other countries either through direct sales or through distributors. Current distributor agreements exist in Canada, Australia, New Zealand, and Pakistan.

We are primarily commercializing our device through one business model, which is ownership accompanied by an annual service and support agreement. In this model, the Swoop® system is typically sold with a service and support agreement that begins in year one and is sold initially in either 36- or 60-month terms. In certain cases, the Swoop® system is sold without an accompanying service and support agreement. We offer our customers payment term options that include, among others, either an upfront payment for the Swoop® system and annual payment for service and support service or an annual payment option for the term of their agreement. The annual payment option contains a portion of interest for the Swoop® system over the term.

This model provides for the sale of the Swoop scanner, along with an off-the-shelf tablet for use with the scanner, to the customer based on agreed payment terms, which is more affordable than the average cost of $1.2 million for conventional MRI scanners.

To a lesser extent, we are also commercializing our device through a subscription bundle model, in which we sell the use of our device and an off-the-shelf tablet for use with the scanner, plus the same service and support benefits provided in the ownership with service and support model. Both the ownership with service and support model and the subscription bundle model are available for commercial and research use of the device.

To help ensure our customers receive the highest level of customer service, we plan to continue to sell directly to customers and provide ongoing customer support. However, as we expand internationally subject to regulatory authorization in those countries, we may continue to leverage distributors to sell our product depending on the commercial strategy for each country assessed on a country-by-country basis. Through our business model, we aim to provide MRI systems that are more affordable than conventional MRI systems and achieve our vision of increasing accessibility to MRI worldwide.

Suppliers and Manufacturing

Our Swoop® system is built using both custom-made and off-the-shelf components supplied by outside manufacturers and vendors located in the United States, Europe and Asia. One key custom-made component in our Swoop® system is the magnet, which is manufactured by a single source supplier in Europe. The majority of the other components for the Swoop® system are off-the-shelf or made using standard processes.

We purchase some of our components and materials used in manufacturing, including magnets, field programmable gate arrays (“FPGAs”), central processing units (“CPUs”) and molded plastics, from single sources. Although we believe that alternative sources of these components and materials would be available, it would take time to identify and validate replacement components, which could negatively affect our ability to supply the Swoop® system on a timely basis. We cannot give assurances that any alternative supplier would be able to recreate the manufacturing processes currently in use. To mitigate this risk, we typically carry a significant inventory of critical components. We are also working with our Swoop® system device manufacturer, Benchmark Electronics, Inc. ("Benchmark"), to add an additional magnet supplier to the manufacturing process to mitigate the risk to supply of our magnets by the current use of a single supplier.

All of our Swoop® system devices are manufactured, tested, shipped and supported by Benchmark from its facilities in Nashua, NH. We believe that this manufacturing strategy is efficient and conserves capital. However, in the event it becomes necessary to utilize a different contract manufacturer for our Swoop® system products, we would experience additional costs, delays and difficulties in doing so, and our business could be harmed.

Key Agreements

Manufacture and Supply Agreement with Benchmark Electronics, Inc.

In October 2018, Legacy Hyperfine entered into a Manufacture and Supply Agreement with Benchmark (the “MSA”). Under the MSA, Benchmark agreed to manufacture our products pursuant to binding purchase orders. Each month, we have agreed to provide Benchmark with a binding purchase order for a period specified by the MSA, as well as a non-binding forecast for each month within

such period. If we do not provide the monthly purchase order and forecast update, then the first forecast month of the then-current forecast becomes binding so that a rolling binding commitment to purchase product for the specified period is maintained. The parties have agreed to meet periodically regarding any minimum order quantities of components under the MSA. We also have certain inventory related obligations, including the obligation to purchase excess and obsolete components from Benchmark. Excess components are determined based upon the amount of component inventory that exceeds the build plan for the specified period discussed above. We would be required to purchase such excess inventory and be credited back against future purchases of finished products as the inventory of components is reduced to the amount needed to meet the rolling build plan. Obsolete materials are immediately invoiced once identified.

Under the terms of the MSA, we granted Benchmark a non-exclusive, non-transferable, revocable, fully-paid, royalty-free license, without the right to sublicense, to use our technology solely to manufacture our products. The MSA provides that we will own any right, title and interest in any improvements or modifications to our technology made in the course of performance of Benchmark's obligations under the MSA. We and Benchmark also agreed to indemnify each other against certain third-party claims.

Following the MSA's initial three-year term, the MSA renews automatically for additional two-year terms unless either party gives 180 days' prior written notice before the end of the then-current term to the other party electing not to renew the agreement. The MSA or any purchase order under the MSA may be terminated by either party for convenience upon 90 days' prior written notice to the other party. The MSA may also be terminated by either party by written notice upon the occurrence of (i) a breach by the other party under the agreement which is not cured within 30 days after written notice by the terminating party, (ii) the other party becomes insolvent, dissolves, liquidates or ceases to conduct business or (iii) the occurrence of payment-related breaches. Benchmark may also terminate the agreement upon the filing of any petition against us under bankruptcy or similar laws, where such petition is not vacated within 10 days via court order.

Competition

Several large companies, such as General Electric, Siemens, Philips, Hologic, Varian, Fuji, Toshiba, Canon and Hitachi currently dominate the medical imaging market. We expect that the existing market participants will remain key players in the future.

As a general matter, we view competition on two levels:

- Computed tomography (CT), particularly non-contrast computed tomography, both portable and/or at the point of care setting. CT systems, while providing valuable information about hemorrhage and fractures, provide less soft tissue differentiation to inform clinical decisions when compared to MRI. As such, Swoop is well positioned to augment critical care and emergency departments with existing CT capabilities; and

- Portable ultra-low field MRI systems with the same or better attributes, currently in development. Currently, to our knowledge these systems have no, or limited market penetration and we are not aware of any competing company that has successfully delivered a commercial, scalable portable MRI system. There are several companies currently in the process of developing this technology, including Promaxo, Neuro42, Deepspin and Huami.

We view high-field MRI more as a complementary than a competitive technology. Particularly in the U.S., we are seeing substantial interest among our customers for the implementation of Swoop® system to augment traditional, high-field MRI workflows and increase throughput of high-field scanners.

Intellectual Property

Protection of our intellectual property is a strategic priority for our business. We rely on a combination of patents, trademarks, trade secrets and other intellectual property rights protections and contractual restrictions to protect our proprietary technologies.

The patents owned and in-licensed by us are generally directed to the architecture of Legacy Hyperfine's MRI systems and related technology, and Liminal's non-invasive brain sensing and treatment devices and related technology. We have developed a portfolio of issued patents and pending patent applications directed to commercial products and technologies for potential development. We believe that our intellectual property is a core strength of our business, and our strategy includes the continued development of our patent portfolio.

Our Swoop® System and Related Technology

As of February 15, 2023, Hyperfine owned approximately 142 issued patents and approximately 108 pending patent applications relating to our Swoop® System and related technology. Of Legacy Hyperfine's approximately 141 issued patents, approximately 103 were issued U.S. patents. Of Legacy Hyperfine's approximately 108 pending patent applications, approximately 40 were pending U.S. patent applications. In addition, Hyperfine owned approximately 39 issued patents in foreign jurisdictions, including Australia, China, France, Germany, Ireland, Israel, Japan, Korea, the Netherlands, Switzerland/Liechtenstein, and the United Kingdom, and approximately 68 pending patent applications in foreign jurisdictions, including China, Europe and the Patent Cooperation Treaty (PCT) countries, corresponding to the foregoing. In total, Hyperfine owns approximately 69 patent families generally directed to its MRI system, including magnet design and manufacturing, electronics and circuitry, mechanical aspects, safety features, noise compensation technology, image formation and analysis software, and various other aspects of MRI systems. These issued patents and pending patent applications (if they were to issue as patents) have expected expiration dates ranging between 2035 and 2043.

Liminal Non-Invasive Brain Sensor and Related Technology

As of February 15, 2023, Liminal owned approximately 7 pending patent applications. Of Liminal's approximately 3 pending patent applications, approximately 3 were pending U.S. utility patent applications. These applications are directed to its brain sensing technology, including stimulation and monitoring components, electronics and circuitry, mechanical aspects, and software including AI software algorithms, and various additional features. These pending patent applications (if they were to issue as patents) have expected expiration dates ranging between 2039 and 2041.

In addition to patents, we also rely on trade secrets, technical know-how, and continuing innovation to develop and maintain our competitive position. We seek to protect our proprietary information and other intellectual property by generally requiring our employees, consultants, contractors, suppliers, outside scientific collaborators and other advisors to execute non-disclosure and assignment of invention agreements on commencement of their employment or engagement. Agreements with our employees also forbid them from using or incorporating the proprietary rights of third parties during their engagement with us. We also generally require confidentiality or material transfer agreements from third parties that receive our confidential data or materials.

License Agreements

We have entered into licenses in the ordinary course of business relating to our technologies or other intellectual property rights or assets.

Exclusive License Agreements with The General Hospital Corporation (d/b/a Massachusetts General Hospital)

Legacy Hyperfine entered into an exclusive license agreement with The General Hospital Corporation (d/b/a Massachusetts General Hospital) ("MGH") effective in May 2014 (the "May Agreement") and an exclusive license agreement with MGH effective in June 2014 (the "June Agreement"), respectively, under each of which Legacy Hyperfine acquired an exclusive and worldwide license to specified patent rights owned by MGH relating to MRI technology. The licenses were granted to us subject to the right of MGH and not-for-profit academic, government and other not-for-profit institutions to make and to use the subject matter described or claimed in the rights granted under the licensed patents for research and educational purposes and, for any licensed patents that are supported by federal funding, subject to certain rights, conditions and limitations imposed by U.S. law, including a royalty-free, non-exclusive license granted to the U.S. government and a requirement that any products used or sold in the United States must be manufactured substantially in the United States.

Under the terms of each of the license agreements, we agreed to pay MGH an annual maintenance fee and agreed to reimburse MGH for certain patent related fees and costs incurred by MGH, including past patent fees and costs. If we were to enter into a sublicense under either license agreement, we would be obligated to pay MGH a percentage in the mid-teens of certain consideration paid to us by the sublicensee. The aggregate amount we paid under these agreements was $98,000.

At the end of the third quarter of 2022, we provided MGH with written notice that we were terminating our license agreements effective in the fourth quarter of 2022. The licensed patents are not used in our current products and we do not expect to use them in future products.

Government Regulation

Diagnostic and therapeutic medical devices like those we develop and distribute are subject to regulation by numerous regulatory bodies, including the U.S. Food and Drug Administration ("FDA") and comparable international regulatory agencies. These agencies require developers of medical devices to comply with applicable laws and regulations governing the development, testing, manufacturing, packaging, labeling, marketing and distribution of medical devices. Devices are generally subject to varying levels of regulatory control, the most comprehensive of which requires that a clinical evaluation program be conducted before a device can be approved for marketing and commercial distribution. In addition, healthcare regulatory bodies in the United States and around the world impose a range of requirements related to paying for medical devices and the procedures in which they are used, including laws intended to prevent fraud, waste, and abuse of healthcare dollars.

U.S. Laws and Regulations

In the United States, medical devices are subject to extensive regulation at the federal level by the FDA under the Federal Food, Drug, and Cosmetic Act ("FDCA") and its implementing regulations. The laws and regulations govern, among other things, medical device design and development, nonclinical and clinical testing, pre-market clearance, authorization or approval, establishment registration and product listing, product manufacturing, product packaging and labeling, product storage, advertising and promotion, product distribution, recalls and field actions, servicing and post-market clinical surveillance. A number of U.S. states also impose licensing and compliance regimes on companies that manufacture or distribute prescription devices into or within the state.

Some of our products are also subject to the Radiation Control for Health and Safety Act, administered by the FDA, which imposes performance standards and record keeping, reporting, product testing and product labeling requirements for electronic products that emit radiation, such as magnetic resonance imaging systems.

In addition, the commercialization and use of our devices in the United States is subject to regulation by the U.S. Department of Health and Human Services ("HHS") and state agencies responsible for reimbursement and regulation of payment for healthcare items and services. Federal laws and regulations apply primarily in connection with government payer programs such as the Medicare and Medicaid programs, but state laws apply more broadly, encompassing healthcare items and services covered by private payers. At the state and federal level, the government's interest is in regulating the quality and cost of healthcare and protecting the independent clinical judgment of licensed healthcare providers.

The Federal Trade Commission ("FTC") also oversees the advertising and promotion of our products pursuant to broad authority to police deceptive advertising for goods or services within the United States. Under the Federal Trade Commission Act, the FTC is empowered, among other things, to (a) prevent unfair methods of competition and unfair or deceptive acts or practices in or affecting commerce; (b) seek monetary redress and other relief for conduct injurious to consumers; and (c) gather and compile information and conduct investigations relating to the organization, business, practices, and management of entities engaged in commerce. In the context of performance claims for products such as our goods and services, compliance with the FTC Act includes ensuring that there is scientific data to substantiate the claims being made, that the advertising is neither false nor misleading, and that any user or expert testimonials or endorsements we or our agents disseminate related to the goods or services comply with applicable disclosure rules and other regulatory requirements. In addition, with respect to our commercial products and any future products that are marketed as clinical products, FDA's regulations applicable to medical device products prohibit them from being promoted for uses not within the scope of a given product's authorized intended use(s), among other promotional and labeling rules applicable to products subject to the FDCA.

Further, medical device systems that include wireless radio frequency transmitters and/or receivers are subject to equipment authorization requirements in the United States. The Federal Communications Commission ("FCC") requires advance clearance of all radio frequency devices before they can be sold or marketed in the United States. These clearances ensure that the proposed products comply with FCC radio frequency emission and power level standards and will not cause interference.

FDA Regulation of Medical Devices

Medical devices must undergo pre-market review by and receive clearance, authorization, or approval from the FDA prior to commercialization, unless the device is of a type exempted from such review by statute, regulation, or an FDA exercise of enforcement discretion. The FDA classifies medical devices into three classes based on risk. Regulatory control increases from Class I (lowest risk) to Class III (highest risk). The FDA generally must clear or approve the commercial sale of most new medical devices that fall within product categories designated as Class II and III. Commercial sales of most Class II and III medical devices within the United States must be preceded either by pre-market notification and FDA clearance pursuant to Section 510(k) of the FDCA (Class II) or by the granting of a pre-market approval ("PMA") (Class III), after a pre-market application is submitted. Both 510(k) notifications and PMA applications must be submitted to FDA with significant user fees, although reduced fees for small businesses are available. Class I devices are generally exempt from pre-market review and notification, as are some moderate-risk Class II devices. Manufacturers of all classes of devices must comply with FDA's Quality System Regulation ("QSR"), establishment registration, medical device listing, labeling requirements, and medical device reporting ("MDR") regulations, which are collectively referred to as medical device general controls. Class II devices may also be subject to special controls such as performance standards, post-market surveillance, FDA guidelines, or particularized labeling. Some Class I and Class II devices may be exempted by regulation from the requirement of compliance with substantially all of the QSR.

510(k) Clearance Pathway

A 510(k) pre-market notification must contain information sufficient to demonstrate that the new device is substantially equivalent to a predictive device. A predicate device is a legally marketed device that is not subject to a PMA, meaning, (i) a device that was legally marketed prior to May 28, 1976 ("preamendments device") and for which a PMA is not required, (ii) a device that has been reclassified from Class III to Class II or I, or (iii) a device that was found substantially equivalent through the 510(k) process. To obtain 510(k) clearance for a non-exempt Class II device, the product developer must submit a pre-market notification to FDA demonstrating that its product is substantially equivalent to such a predicate device. The FDA's 510(k) clearance process generally takes from three to five months from the date the application is submitted, but it may take significantly longer if FDA has significant questions or needs more information about the new device or its manufacturing or quality controls.

As part of the 510(k) notification process for Class II devices that have an existing classification regulation available for purposes of the regulatory filing, the FDA may require the following:

- Development of comprehensive product description and indications for use.
- Completion of extensive nonclinical tests and/or animal studies, performed in accordance with the FDA's good laboratory practice ("GLP") regulations, as well as any performance standards or other testing requirements established by FDA through regulations or device-specific guidance.
- Comprehensive review of one or more predicate devices and development of data supporting the new product's substantial equivalence to such predicate devices.

Assuming successful completion of all required testing, a detailed 510(k) notification is submitted to the FDA requesting clearance to market the product. This premarket notification includes all relevant data from pertinent nonclinical studies and clinical trials (if applicable), together with detailed information relating to the product's proposed labeling, and other relevant documentation. The FDA evaluates all 510(k) submissions prior to filing for substantive review based on specific acceptance criteria and may issue a refuse-to-accept notification if the submission is deficient with respect to any of the established criteria. If the FDA determines that the applicant's device is substantially equivalent to the identified predicate device(s), the agency will issue a 510(k) clearance letter that authorizes commercial marketing of the device for one or more specific indications for use. If the FDA determines that the applicant's device is not substantially equivalent to the predicate device(s), the agency will issue a not-substantially-equivalent letter stating that the new device may not be commercially distributed.

After a new medical device receives 510(k) clearance from the FDA, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new 510(k) clearance or could require the submission of a PMA application. The FDA requires each manufacturer to make the determination of whether a device modification requires a new 510(k) notification or PMA in the first instance, but the FDA may review any such decision. If the FDA disagrees with a manufacturer's decision not to seek a new 510(k) clearance or PMA for a particular change, the FDA may retroactively require the manufacturer to submit a 510(k) pre-market notification or a PMA application. The FDA may also require the manufacturer to cease U.S. marketing and/or recall any distributed units of the modified device until 510(k) clearance or a PMA for the modification is obtained.

De Novo Classification

If a previously unclassified new medical device does not qualify for the 510(k) pre-market notification process because no predicate device to which it is substantially equivalent can be identified, the device is automatically classified into Class III. However, if such a device would be considered low or moderate risk (in other words, it does not rise to the level of requiring PMA), it may be eligible for the De Novo classification process. The De Novo classification process allows a device developer to request that the novel medical device be reclassified as either a Class I or Class II device, rather than having it regulated as a high-risk Class III device subject to the PMA requirements. If the manufacturer seeks reclassification into Class II, the classification request must include a draft proposal for special controls that are necessary to provide a reasonable assurance of the safety and effectiveness of the medical device.

Under the FDCA, the FDA is required to classify a device within 120 days following receipt of the De Novo classification request from an applicant; however, the most recent FDA performance review goals state that in fiscal year 2023, FDA will attempt to issue a decision within 150 days of receipt on 70% of De Novo requests received during fiscal year 2023. De Novo classification requests are subject to user fees, unless a specific exemption applies.

As with the 510(k) pre-market notification process described above, any modification to a device authorized through the De Novo process that could significantly affect the safety or effectiveness of such device, or that would constitute a major change in its intended use, requires a new 510(k) clearance or could require the submission of a PMA application.

As an alternative to the De Novo classification process, a company could also file a reclassification petition seeking to change the automatic Class III designation of a novel post-amendment device under Section 513(f)(3) of the FDCA. FDA can also initiate reclassification of an existing device type on its own initiative. In December 2018, FDA issued a final rule to clarify the administrative process through which the FDA reclassifies a medical device. To reclassify a device under Section 513(e) of the FDCA, the FDA must first publish a proposed reclassification order that includes a summary of the valid scientific evidence that supports the reclassification; convene a device classification panel meeting; and consider comments to the public docket before it then publishes a final reclassification order in the Federal Register.

Pre-market Approval Pathway

Our point-of-care MRI systems have been classified and are regulated as Class II devices, although future products that we develop may be classified as Class III devices. Products classified by FDA as Class III generally require marketing approval via the PMA process. A PMA application must be supported by valid scientific evidence, which typically requires extensive data, including technical, nonclinical, clinical, manufacturing and labeling data, to demonstrate to the FDA's satisfaction the safety and efficacy of the device for its intended use(s). A PMA application also must include a complete description of the device and its components, a detailed description of the methods, facilities and controls used to manufacture the device, and proposed labeling. After a PMA application is submitted and found to be sufficiently complete, it is considered "filed" and the FDA begins an in-depth review of the submitted information. During this substantive review period, the FDA may request additional information or clarification of information already provided. Also, during the review period, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA. In addition, the FDA generally will conduct a pre-approval inspection of the manufacturing facility to evaluate compliance with the QSR, which requires manufacturers to implement and follow design, testing, control, documentation and other quality assurance procedures.

FDA review of a PMA application is required to be completed within 180 days of the application's filing date although the process generally takes between one and three years, but may take significantly longer. The FDA can delay, limit or deny approval of a PMA application for many reasons, including:

- the product may not be safe or effective for its intended use(s) to the FDA's satisfaction;
- the data from the applicant's nonclinical studies and clinical trials may be insufficient to support approval;
- the manufacturing process or facilities that the applicant uses may not meet applicable requirements; and
- changes in FDA approval policies or adoption of new regulations may require additional data to demonstrate the safety or effectiveness of the device.

If an FDA evaluation of a PMA application or manufacturing facilities is favorable, the FDA will either issue an approval letter or an approvable letter, which usually contains a number of conditions which must be met in order to secure final approval of the PMA application.

When and if the conditions of the approvable letter have been fulfilled to the satisfaction of the FDA, the agency will issue a PMA approval letter authorizing commercial marketing of a device, subject to the conditions of approval and the limitations established in the approval letter. If the FDA's evaluation of a PMA application or manufacturing facilities is not favorable, the FDA will deny approval of the PMA or issue a not approvable letter. The FDA may also determine that additional clinical trials are necessary, in which case the PMA approval may be delayed for several months or years while the trials are conducted, and data is submitted in an amendment to the PMA. The PMA process can be expensive, uncertain and lengthy. PMA approval may also be granted with post-approval requirements such as the need for additional patient follow-up for an indefinite period of time.

New PMA applications or PMA supplements may be required for modifications to the manufacturing process, labeling, device specifications, materials or design of a device that is approved through the PMA process. PMA supplements often require submission of the same type of information as an initial PMA application, except that the supplement is limited to information needed to support any changes from the device covered by the approved PMA application and may or may not require as extensive clinical data or the convening of an advisory panel.

Clinical Investigations Using Devices in Development

Clinical trials are almost always required to support a PMA application and are sometimes required for a De Novo classification request or 510(k) pre-market notification. In order to conduct a clinical investigation involving human subjects for the purpose of demonstrating the safety and effectiveness of a medical device, an investigator acting on behalf of the company must, among other things, apply for and obtain institutional review board ("IRB") approval of the proposed investigation. In addition, if the clinical trial involves a "significant risk" (as defined by the FDA) to human health, the company sponsoring the trial (referred to as the "sponsor") must also submit and obtain FDA approval of an investigational device exemption ("IDE") application. An IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE application must be approved in advance by the FDA for a specified number of trial participants, unless the product is deemed a non-significant risk device and eligible for abbreviated IDE requirements. Generally, clinical trials for a significant risk device may begin once the IDE application is approved by the FDA and the trial protocol and informed consent are approved by a duly-appointed IRB for each site. FDA's IDE regulations govern investigational device labeling, prohibit promotion, and specify an array of good clinical practice ("GCP") requirements, which include, among other things, recordkeeping, reporting and monitoring responsibilities of trial sponsors and study investigators. Clinical trials must further comply with the FDA's regulations for IRB approval and for informed consent and other human subject protections, all of which are considered part of GCP requirements. Required records and reports are subject to inspection by the FDA. The results of clinical testing may be unfavorable or, even if the intended safety and efficacy success criteria are achieved, may not be considered sufficient for the FDA to grant approval or clearance of a product.

Information about certain clinical trials, including details of the protocol and eventually results, also must be submitted within specific timeframes to the National Institutes of Health, or NIH, for public dissemination on the ClinicalTrials.gov data registry. Information related to the product, patient population, phase of investigation, trial sites and investigators and other aspects of the clinical trial is made public as part of the registration process. Sponsors are obligated to disclose the results of their clinical trials after completion. Disclosure of results can be delayed in some cases for up to two years after the date of completion of the trial. Failure to timely register a covered clinical trial or to submit results as provided for in the law can give rise to civil monetary penalties and also prevent the non-compliant party from receiving future grant funds from the federal government. The NIH Final Rule on ClinicalTrials.gov registration and reporting requirements became effective in 2017, and both NIH and FDA have brought enforcement actions against non-compliant sponsors.

The commencement or completion of any of our clinical trials may be delayed or halted, or be inadequate to support approval of a PMA application (or FDA's grant of a De Novo classification request or clearance of a 510(k) notification, as applicable), for numerous reasons, including, but not limited to, the following:

- the FDA, the IRB(s), or other regulatory authorities do not approve a clinical trial protocol or a clinical trial, or place a clinical trial on hold;
- participants do not enroll in clinical trials at the expected rate;
- participants do not comply with trial protocols;
- participant follow-up is not at the expected rate;
- patients experience adverse side effects;
- participants die during a clinical trial, even though their death may not be related to the investigational products;

- IRBs and third-party clinical investigators may delay or reject the sponsor's trial protocol;
- third-party clinical investigators decline to participate in a trial or do not perform a trial on the sponsor's anticipated schedule or consistent with the clinical trial protocol, GCPs or other FDA requirements;
- the sponsor or third-party organizations do not perform data collection, monitoring and analysis in a timely or accurate manner or consistent with the clinical trial protocol or investigational or statistical plans;
- third-party clinical investigators have significant financial interests related to the sponsor or the trial that the FDA deems to make the trial results unreliable, or the sponsor or investigators fail to disclose such interests;
- unfavorable regulatory inspections of the sponsor's clinical trial sites or manufacturing facilities, which may, among other things, require the sponsor to undertake corrective action or suspend or terminate the sponsor's clinical trials;
- changes in governmental regulations or administrative actions applicable to the sponsor's trial protocols;
- the interim or final results of the clinical trial are inconclusive or unfavorable as to safety or effectiveness; and
- the FDA concludes that the results from the sponsor's trial and/or trial design are inadequate to demonstrate safety and effectiveness of the product.

In the Consolidated Appropriations Act for 2023, Congress amended the FDCA to require the sponsor of any clinical trial for a medical device to develop a diversity action plan for such trial, and if submission of an IDE application is required, to submit such diversity action plan to the FDA. The action plan must include the sponsor's diversity goals for enrollment, as well as a rationale for the goals and a description of how the sponsor will meet them. The FDA may grant a waiver for some or all of the requirements for a diversity action plan. It is unknown at this time how the diversity action plan may affect device clinical trial planning and timing or what specific information FDA will expect in such plans, but if FDA objects to a sponsor's diversity action plan and requires the sponsor to amend the plan or take other actions, it may delay trial initiation.

Ongoing Post-Market Regulatory Requirements and FDA Enforcement

In 2020, Legacy Hyperfine received 510(k) clearance from the FDA for its point-of-care MRI system. In addition, our proprietary BrainInsight product is fully automated MRI post-processing medical software that is regulated as a picture archiving and communications system, a classification which may include both hardware and software components, and which is classified by FDA as a Class II medical device. BrainInsight received 510(k) marketing clearance in January 2021 for use in automatic labeling, spatial measurement, and volumetric quantification of brain structures from a set of low-field MR images and to return annotated and segmented images, color overlays, and reports. More recently, in December 2022, Hyperfine received clearance for BrainInsight to include pediatric patients aged two years and older for lateral ventricles and midline shift applications. In December 2022, Hyperfine also received clearance for modifications to the MRI system, including software modifications related to the device pulse sequences and retraining of the advanced reconstruction models.

After a medical device is authorized for marketing and placed in commercial distribution (or, for 510(k)-exempt products, placed into commerce without first obtaining FDA clearance or approval), numerous regulatory requirements apply. These general controls that must be met for all device classes include:

- establishment registration and device listing;
- the QSR, which requires manufacturers, including third-party manufacturers, to follow design, testing, control, storage, supplier/contractor selection, complaint handling, documentation and other quality assurance procedures;
- labeling regulations, which govern the mandatory elements of the device labels and packaging (including Unique Device Identifier markings for certain categories of products);
- FDA's prohibitions against the promotion of products for uncleared, unapproved or "off-label" uses and other requirements related to promotional activities;
- the MDR regulations, which require that manufacturers report to the FDA if a device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur;
- voluntary and mandatory device recalls to address problems when a device is defective and/or could be a risk to health;

- correction and removal reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health; and
- post-market surveillance regulations, which apply to certain Class II or III devices when necessary to protect the public health or to provide additional safety and effectiveness data for the device.

FDA's MDR requirements also extend to healthcare facilities that use medical devices in providing care to patients, or "device user facilities," which include hospitals, ambulatory surgical facilities, nursing homes, outpatient diagnostic facilities, or outpatient treatment facilities, but not physician offices. A device user facility must report any device-related death to both the FDA and the device manufacturer, or any device-related serious injury to the manufacturer (or, if the manufacturer is unknown, to the FDA) within 10 days of the event. Device user facilities are not required to report device malfunctions that would likely cause or contribute to death or serious injury if the malfunction were to recur but may voluntarily report such malfunctions through MedWatch, the FDA's Safety Information and Adverse Event Reporting Program.

To ensure compliance with regulatory requirements, medical device manufacturers are subject to market surveillance and periodic, pre-scheduled and unannounced inspections by the FDA and certain state authorities. Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may lead to any of the following sanctions:

- Warning Letters or Untitled Letters that require corrective action;
- fines and civil penalties;
- unanticipated expenditures;
- delays in approving/clearing or refusal to approve/clear any of our future products;
- FDA refusal to issue certificates to foreign governments needed to export our products for sale in other countries;
- suspension or withdrawal of FDA approval or clearance (as may be applicable);
- product recall or seizure;
- partial suspension or total shutdown of production;
- operating restrictions;
- injunctions or consent decrees; and
- civil or criminal prosecution.

We and any of our contract manufacturers, and some suppliers of components or device accessories, are required to manufacture medical device products in compliance with current good manufacturing practice requirements set forth in the QSR, unless explicitly exempted by regulation. The QSR requires a quality system for the design, manufacture, packaging, labeling, storage, installation and servicing of marketed devices, and includes extensive requirements with respect to quality management and organization, device design, buildings, equipment, purchase and handling of components or services, production and process controls, packaging and labeling controls, device evaluation, distribution, installation, complaint handling, servicing, and record keeping. The FDA evaluates compliance with the QSR through periodic pre-scheduled or unannounced inspections that may include registered manufacturing facilities of our subcontractors. Following such inspections, FDA may issue reports known as Forms FDA 483 or Notices of Inspectional Observations, which list instances where the FDA inspector believes the manufacturer has failed to comply with applicable regulations and/or procedures. If the observations are sufficiently serious or the manufacturer fails to respond appropriately, the FDA may issue Warning Letters, which are notices of intended enforcement actions against the manufacturer. For less serious violations that may not rise to the level of regulatory significance, FDA may issue Untitled Letters. FDA may take more significant administrative or legal action if a manufacturer continues to be in substantial noncompliance with applicable regulations.

For example, if the FDA believes we or any of our contract manufacturers or regulated suppliers are not in compliance with these requirements and patients are being subjected to serious risks, it can shut down manufacturing operations, require recalls of our medical device products, refuse to approve new marketing applications, initiate legal proceedings to detain or seize products, enjoin future violations, or assess civil and criminal penalties against us or our officers or other employees. Any such action by the FDA would have a material adverse effect on our business. We may be unable to comply with all applicable FDA regulations.

U.S. Fraud and Abuse Laws and Other Compliance Requirements

Successfully commercializing a medical device or technology depends not on only FDA approval, but also on broad health insurance or third-party payor coverage. Government and private payors institute coverage criteria to ensure the appropriate utilization of products and services and to control costs. Limited third-party payor coverage for a technology or procedure may limit adoption and commercial viability, while broader coverage supports optimal market uptake. Favorable coverage decisions by government payors like Medicare or Medicaid is critical because private payors typically follow the government's lead regarding reimbursement. However, manufacturers whose technology is reimbursed by government payors are subject to various U.S. federal and state laws pertaining to healthcare fraud and abuse. These laws can be implicated by inappropriate sales and marketing arrangements with healthcare providers. Many commonly accepted commercial practices are illegal in the healthcare industry and violations of these laws are punishable by criminal and civil sanctions, including, in some instances, exclusion from participation in U.S. federal and state healthcare programs, including Medicare and Medicaid.

Anti-kickback Laws. The federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, receiving, offering or providing remuneration directly or indirectly to induce either the referral of an individual, or the furnishing, recommending, or arranging of a good or service, for which payment may be made under a government healthcare program such as Medicare and Medicaid. The definition of "remuneration" has been broadly interpreted to include anything of value, including such items as gifts, discounts, the furnishing of supplies or equipment, credit arrangements, waiver of payments, and providing anything at less than its fair market value. The Office of the Inspector General for the U.S. Department of Health and Human Services, has issued regulations, commonly known as safe harbors, which set forth certain provisions that, if satisfied in their entirety, will assure healthcare providers and other parties that they will not be prosecuted under the federal Anti-Kickback Statute. The failure of a transaction or arrangement to fit precisely within one or more safe harbors does not necessarily mean that it is illegal or that prosecution will be pursued. However, conduct and business arrangements that do not fully satisfy each applicable safe harbor element may result in increased scrutiny by government enforcement authorities or invite litigation by private citizens under federal whistleblower laws. The Anti-Kickback law is broadly interpreted and aggressively enforced with the result that beneficial commercial arrangements can be criminalized in the healthcare industry because of the Anti-Kickback law.

The penalties for violating the federal Anti-Kickback Statute include imprisonment for up to ten years, fines of up to $100,000 per violation and possible exclusion from government healthcare programs such as Medicare and Medicaid. Many states have adopted prohibitions similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare services reimbursed by any source, not only by the government programs such as Medicare and Medicaid.

Federal False Claims Act. The federal False Claims Act prohibits knowingly presenting, or causing to be presented a false claim or the knowing use of false statements or records to obtain payment from the federal government. When an entity is determined to have violated the False Claims Act, it must pay three times the actual damages sustained by the government, plus mandatory per-claim civil penalties and attorneys' fees. Violation of the False Claims Act also can result in exclusion from government healthcare programs.. Suits filed under the False Claims Act, known as "qui tam" actions, can be brought by any individual on behalf of the government and such individuals (known as "relators" or, more commonly, as "whistleblowers") may share in any amounts paid by the entity to the government in fines or settlement. In addition, certain states have enacted laws modeled after the federal False Claims Act. Qui tam actions have increased significantly in recent years, causing greater numbers of healthcare companies to have to defend a false claim action, even before the validity of the claim is established and even if the government decides not to intervene in the lawsuit. Healthcare companies may decide to agree to large settlements with the government and/or whistleblowers to avoid the cost and negative publicity associated with litigation. In addition, the Patient Protection and Affordable Care Act of 2010 amended federal law to provide that a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. Criminal prosecution is possible for knowingly making or presenting a false or fictitious or fraudulent claim to the federal government.

Various states have enacted false claims laws analogous to the False Claims Act. Some of these state laws apply where a claim is submitted to any commercial payor, and not merely a government healthcare program, and some authorize private citizens to bring suit on the state's behalf.

Federal Physician Self-Referral Law. The Federal Physician Self-Referral Law, also referred to as the Stark Law, prohibits a physician (or an immediate family member of a physician) who has a financial relationship with an entity from referring patients to that entity for certain designated health services, including durable medical equipment and supplies, payable by Medicare, unless an exception applies. The Stark Law also prohibits such an entity from presenting or causing to be presented a claim to the Medicare program for such designated health services provided pursuant to a prohibited referral, and provides that certain collections related to any such claims must be refunded in a timely manner. Exceptions to the Stark Law include, among other things, exceptions for certain financial relationships, including both ownership and compensation arrangements. The Stark Law is a strict liability statute: to the extent that the statute is implicated and an exception does not apply, the statute is violated. In addition to the Stark Law, many states have implemented similar physician self-referral prohibitions that may extend to Medicaid, third-party payors, and self-pay patients. Violations of the Stark Law must be reported and unauthorized claims must be refunded to Medicare in order to avoid potential liability under the federal False Claims Act for avoiding a known obligation to return identified overpayments. Violations of the Stark Law can also form the basis for exclusion from participation in federal and state healthcare programs.

Civil Monetary Penalties Law. The Civil Monetary Penalties Law ("CMPL") authorizes the imposition of substantial civil money penalties against an entity that engages in certain prohibited activities including but not limited to violations of the Stark Law or Anti-Kickback Statute, knowing submission of a false or fraudulent claim, employment of an excluded individual, and the provision or offer of anything of value to a Medicare or Medicaid beneficiary that the transferring party knows or should know is likely to influence beneficiary selection of a particular provider for which payment may be made in whole or part by a government healthcare program, unless an exception applies. Sanctions for violations of the CMPL include exclusion from participation in government healthcare programs, substantial fines, and payment of up to three times the amount billed, depending upon the nature of the offense.

State Analogs of Federal Fraud and Abuse Laws. Many U.S. states have their own laws intended to protect against fraud and abuse in the healthcare industry and more broadly. In some cases these laws prohibit or regulate additional conduct beyond what federal law affects. Penalties for violating these laws can range from substantial fines to criminal sanctions.

HIPAA. The Health Insurance Portability and Accountability Act of 1996 and implementing regulations ("HIPAA"), created two new federal crimes: healthcare fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private payors. A violation of this statute is a felony and may result in fines, imprisonment or exclusion from government healthcare programs. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services.

FCPA and Other Anti-Bribery and Anti-Corruption Laws. The U.S. Foreign Corrupt Practices Act ("FCPA") prohibits U.S. corporations and their representatives from offering, promising, authorizing or making payments to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business abroad. The scope of the FCPA would include interactions with certain healthcare professionals or organizations in many countries. Our present and future business has been and will continue to be subject to various other U.S. and foreign laws, rules and/or regulations.

Physician Payments Sunshine Act. Manufacturers of U.S. FDA-regulated devices reimbursable by government healthcare programs are subject to the Physician Payments Sunshine Act, which requires manufacturers to track and annually report certain payments and other transfers of value made to U.S.-licensed physicians, certain advanced non-physician healthcare practitioners, or U.S. teaching hospitals. As a manufacturer of U.S. FDA regulated devices reimbursable by government healthcare programs, we are subject to this law. We are also required to report certain ownership interests held by physicians and their immediate family members. The law authorizes significant monetary penalties for violations, depending on the circumstances, and payments reported also have the potential to draw scrutiny on payments to and relationships with physicians, which may have implications under the Anti-Kickback Statute, Stark Law and other healthcare laws.

Similar to the federal law, certain states also have adopted marketing and/or transparency laws relevant to device manufacturers, some of which are broader in scope. Some state laws require medical device companies to comply with the relevant industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring device manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures. The need to build and maintain a robust compliance program with different compliance and/or reporting requirements increases the possibility that a healthcare company may violate one or more of the requirements, resulting in fines and penalties

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U.S. and European Data Security and Data Privacy Laws

HIPAA's administrative simplification provisions established comprehensive federal standards for the privacy and security of health information. In 2009, Congress enacted Subtitle D of the Health Information Technology for Economic and Clinical Health Act, or HITECH, provisions of the American Recovery and Reinvestment Act of 2009, which expanded and strengthened HIPAA, created new targets for enforcement, imposed new penalties for noncompliance and established new breach notification requirements. HIPAA applies to health plans, healthcare clearing houses, and healthcare providers that conduct certain healthcare transactions electronically, which are referred to collectively as Covered Entities, as well as individuals or entities that perform services for Covered Entities involving the use, or disclosure of, individually identifiable health information or protected health information ("PHI") under HIPAA. Such service providers are called "Business Associates." Under HIPAA, as amended by the HITECH Act, HHS has issued regulations to protect the privacy and security of PHI used or disclosed by Covered Entities and Business Associates. HIPAA also regulates and standardizes the codes, formats and identifiers used in certain healthcare transactions and standardization of identifiers for health plans and providers, for example insurance billing. We are a Business Associate of our Covered Entity Customers in connection with the use of data and images to train AI algorithms as well as the provision of product maintenance and support services. Accordingly, we execute and must comply with HIPAA Business Associate Agreements and with HIPAA regulations applicable to Business Associates. Any non-compliance with HIPAA and HITECH and related penalties, could adversely impact our business.

The HIPAA security standards require the adoption of administrative, physical, and technical safeguards and the adoption of written security policies and procedures to maintain the security of protected health information.

The HIPAA privacy regulations address the privacy of PHI by limiting the use and release of such information. They also set forth certain rights that an individual has with respect to his or her PHI maintained by a covered entity, including the right to access or amend certain records containing PHI, request an accounting of disclosures of PHI or to request restrictions on the use or disclosure of PHI. Proposed modifications to the privacy regulations were published in January 2021 with a public comment period that ended in May 2021. The content of the final rules and their potential impact on us is unknown at this time. The HIPAA breach notification regulations impose certain reporting requirements on Covered Entities and their Business Associates in the event of a breach of PHI.

Significant civil and criminal fines and other penalties may be imposed for violating HIPAA directly, and in connection with acts or omissions of any agents, including a downstream Business associate, as determined according to the federal common law of agency. Civil penalties are adjusted for inflation on an annual basis and can exceed one million dollars per year for failure to comply with a HIPAA requirement. A single breach incident can violate multiple requirements. Additionally, a person who knowingly obtains or discloses PHI in violation of HIPAA may face a criminal penalties (including fines and imprisonment), which increase if the wrongful conduct involves false pretenses or the intent to sell, transfer or use PHI for commercial advantage, personal gain or malicious harm. Covered Entities are also subject to enforcement by state Attorneys General who were given authority to enforce HIPAA.

Additionally, while HIPAA does not create a private right of action allowing individuals to file suit against us in civil court for violations of HIPAA, its standards have been used as the basis for duty of care cases in state civil suits such as those for negligence or recklessness in the misuse or breach of PHI.

Even when HIPAA does not apply, according to the FTC, failing to take appropriate steps to keep consumers' personal information secure constitutes unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act. The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards. The FTC and states' Attorneys General have also brought enforcement actions and prosecuted some data breach cases as unfair and/or deceptive acts or practices under the FTC Act and comparable state laws.

The HIPAA privacy and security regulations establish a uniform federal "floor" and do not preempt state laws that are more stringent or provide individuals with greater rights with respect to the privacy or security of, and access to, their records containing PHI. These laws overlap with HIPAA and may differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. The State of California, for example, has implemented comprehensive laws and regulations. The California Confidentiality of Medical Information Act (CMIA), imposes restrictive requirements regulating the use and disclosure of health information and other personally identifiable information. The California Consumer Privacy Act of 2018 (the CCPA) went into effect January 1, 2020. The CCPA, among other things, creates new data privacy obligations for covered companies and provides

new privacy rights to California residents, including the right to opt out of certain disclosures of their information. It also creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches which has led to an increase data breach litigation. Although the law includes limited exceptions, including for PHI maintained by a covered entity or business associate under HIPAA and medical information maintained by healthcare providers under the CMIA, it may regulate or impact our processing of personal information depending on the context. Further, the California Privacy Rights Act (CPRA) went into effect January 1, 2023, amending the CCPA. The CPRA imposes additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data and expands the application of the CCPA to all human resources personal information of California-based employees. It also created a new California data protection agency authorized to issue substantive regulations and is expected to result in increased privacy and information security enforcement. Similar to California, Virginia, Colorado, Connecticut, and Utah all enacted similar omnibus privacy laws that will also take effect in 2023, increasing the complexity of compliance and the risk of failures to comply.

In dealing with health information for the development of our technology or for commercial purposes, we will be indirectly affected by HIPAA and state-imposed health information privacy and security laws because these laws regulate the ability of our customers and research collaborators to share health information with us. Additionally, we must identify and comply with all applicable state laws for the protection of personal information with respect to employee information or other personal information that we collect.

In the European Union, increasingly stringent data protection and privacy rules that have and will continue to have substantial impact on the use of personal and patient data across the healthcare industry became stronger in May 2018. The EU General Data Protection Regulation, (“GDPR”) applies across the European Union and includes, among other things, a requirement for prompt notice of data breaches to data subjects and supervisory authorities in certain circumstances and significant fines for non-compliance. The GDPR fine framework can be up to 20 million euros, or up to 4% of our total global turnover of the preceding fiscal year, whichever is higher. The GDPR sets out a number of requirements that must be complied with when handling the personal data of such European Union-based data subjects including: providing expanded disclosures about how their personal data will be used; higher standards for organizations to demonstrate that they have obtained valid consent or have another legal basis in place to justify their data processing activities; the obligation to appoint data protection officers in certain circumstances; new rights for individuals to be “forgotten” and rights to data portability, as well as enhanced current rights (e.g. access requests); the principal of accountability and demonstrating compliance through policies, procedures, training and audit; and the new mandatory data breach regime. In particular, medical or health data, genetic data and biometric data where the latter is used to uniquely identify an individual are all classified as “special category” data under the GDPR and are afforded greater protection and require additional compliance measures. Noncompliance could result in the imposition of fines, penalties, data lockup or orders to stop noncompliant activities. We may be subject to GDPR if we undertake operations in the EU, offer products or services to individuals in the EU or monitor the behavior of individuals within the EU. Our research activities in the EU currently implicate the GDPR and if we undertake commercial operations in the EU, offer products or services to individuals in the EU or monitor the behavior of individuals within the EU, we will have additional compliance obligations.

We could also be subject to evolving European Union laws on data export, for transfers of data outside the European Union to themselves, group companies or third parties. The GDPR only permits exports of data outside the European Union to jurisdictions that ensure an adequate level of data protection. The United States has not been deemed to offer an adequate level of protection, so in order for us to transfer personal data from the EU to the United States, we must identify a legal basis for data transfer (e.g., the European Union Commission approved Standard Contractual Clauses). On July 16, 2020, the Court of Justice of the European Union or the CJEU, issued a landmark opinion in the case *Maximilian Schrems vs. Facebook* (Case C-311/18), called *Schrems II*. This decision (a) calls into question commonly relied upon data transfer mechanisms as between the European Union member states and the United States (such as the Standard Contractual Clauses) and (b) invalidates the EU-U.S. Privacy Shield on which many companies had relied as an acceptable mechanism for transferring such data from the EU to the United States. The CJEU is the highest court in Europe and the *Schrems II* decision heightens the burden on data importers to assess U.S. national security laws on their business and future actions of European Union data protection authorities are difficult to predict.

Relatedly, following the United Kingdom's withdrawal from the EU, the GDPR has been implemented in the United Kingdom (as the UK GDPR). The UK GDPR sits alongside the UK Data Protection Act 2018 which implements certain derogations in the EU GDPR into United Kingdom law. Under the UK GDPR, companies not established in the United Kingdom but who process personal data in relation to the offering of goods or services to individuals in the United Kingdom, or monitor the behavior of individuals in the United Kingdom will be subject to the UK GDPR – the requirements of which are (at this time) largely aligned with those under the EU GDPR and as such, may lead to similar compliance and operational costs with potential fines of up to 17.5 million pounds sterling or 4% of global turnover, whichever is higher. On June 28, 2021, the European Commission issued a decision that the United Kingdom ensures an adequate level of protection for personal data transferred under the EU GDPR from the European Union to the United Kingdom. In 2022, the UK government proposed and debated the Data Protection and Digital Information Bill to harmonize the 2018 Data Protection Act, UK GDPR, and the Privacy and Electronic Communications Regulations under one legislative framework. However, progress on the bill stalled as the government continues to assess the most optimal approach to data protection reform.

International Regulation of Medical Devices

International marketing and distribution of medical devices are subject to regulation by foreign governments, and such regulations may vary substantially from country to country. The time required to obtain marketing authorization in a foreign country may be longer or shorter than that required for FDA clearance or approval, and the requirements may differ. There is a trend towards harmonization of quality system standards among the European Union, United States, Canada and various other industrialized countries.

The primary regulatory environment in Europe is that of the European Economic Area (the "EEA"), which is comprised of the 27 Member States of the European Union (the "EU"), Iceland, Liechtenstein and Norway. In the EEA, medical devices were previously required to comply with the Essential Requirements defined in Annex I to the EU Medical Devices Directive ("MDD") (applicable in the non-EU EEA Member States via the Agreement on the European Economic Area), a coordinated system for the authorization of medical devices. The directives and standards outlined in the MDD regulate the design, manufacture, clinical trials, labeling and adverse event reporting for medical devices. Devices that comply with the requirements of a relevant directive are entitled to bear the CE conformity marking, indicating that the device conforms to the essential requirements of the applicable directives and, accordingly, can be commercially distributed throughout the EEA. The method of assessing conformity varies depending on the class of the product, but normally involves a combination of self-assessment by the manufacturer and a third-party assessment by a "Notified Body," an organization designated by an EU country to assess a product's conformity with the applicable legal requirements. This third-party assessment may consist of an audit of the manufacturer's quality system and specific testing of the manufacturer's product. An assessment by a Notified Body of one country within the EU is required in order for a manufacturer to commercially distribute the product throughout the EU.

In 2017, European Union regulatory bodies finalized a new Medical Device Regulation, which replaced the existing MDD framework and became effective on May 26, 2021. The Medical Device Regulation changes several aspects of the existing regulatory framework for medical device marketing in Europe and is expected to result in increased regulatory oversight of all medical devices marketed in the EU, which may, in turn, increase the costs, time and requirements that need to be met in order to place an innovative or high-risk medical device on the European market. In particular, the new regulations, among other things:

- strengthen the rules on placing devices on the market and reinforce surveillance once they are available;
- establish explicit provisions on manufacturers' responsibilities for the follow-up of the quality, performance and safety of devices placed on the market;
- improve the traceability of medical devices throughout the supply chain to the end-user or patient through a unique identification number;
- set up a central database to provide patients, healthcare professionals and the public with comprehensive information on products available in the EU; and
- strengthen the rules for the assessment of certain high-risk devices, which may have to undergo an additional check by experts before they are placed on the market.

European medical device manufacturers and distributors are currently benefiting from a grace period for legacy MDD certificates that lasts until May 26, 2024. For a product to qualify for the grace period, there must be no significant changes to such a legacy medical device as described in its existing MDD certificate; the recertification process under the Medical Device Regulation requires a demonstration that the performance and the safety of the currently marketed medical device has been maintained and that the system meets the new regulatory requirements.

Outside of the EU, regulatory authorization must be sought on a country-by-country basis in order for the company to market their products. Some countries have adopted medical device regulatory regimes, such as the Classification Rules for Medical Devices published by the Hong Kong Department of Health, the Health Sciences Authority of Singapore regulation of medical devices under the Health Products Act, and Health Canada's risk classification system for invasive devices, among others. Each country may have its own processes and requirements for medical device licensing, approval/clearance, and regulation, therefore requiring the company to seek marketing authorizations on a country-by-country basis.

In addition, as previously noted, the UK left the EU on January 31, 2020, with a transitional period that expired on December 31, 2020. The United Kingdom and the European Union entered into a trade agreement known as the Trade and Cooperation Agreement ("TCA"), which came into effect on January 1, 2021. The TCA does not specifically refer to medical devices. However, as a result of Brexit, the Medical Device Regulation will not be implemented in the UK, and previous legislation that mirrored the Medical Device Regulation in the UK law has been revoked. The regulatory regime for medical devices in the UK will continue to be based on the requirements derived from EU legislation as of January 21, 2020, and the UK may choose to retain regulatory flexibility or align with the Medical Device Regulation going forward. CE markings will continue to be recognized in the UK, and certificates issued by EU recognized Notified Bodies will be valid in the UK, until June 30, 2023. For medical devices placed on the UK market after this period, the UK Conformity Assessment UKCA marking will be mandatory. In contrast, UKCA marking and certificates issued by UK Notified Bodies will not be recognized on the EU market. The TCA does provide for cooperation and exchange of information in the area of product safety and compliance, including market surveillance, enforcement activities and measures, standardization related activities, exchanges of officials, and coordinated product recalls (or other similar actions). Depending on which countries products will ultimately be sold in, manufacturers may start seeking alternative sources for components if this would allow them to benefit from no tariffs. The rules for placing medical devices on the Northern Ireland market will differ from those in the UK.

In addition, outside the United States, a range of anti-bribery and anti-corruption laws, as well as some industry-specific laws and codes of conduct, apply to the medical device industry and interactions with government officials and entities and healthcare professionals. Such laws include, but are not limited to the UK Bribery Act of 2010. Further, the European Union member countries have emphasized a greater focus on healthcare fraud and abuse and have indicated greater attention to the industry by the European Anti-Fraud Office. Countries in Asia have also become more active in their enforcement of anti-bribery laws and with respect to procurement and supply chain fraud.

Corporate Information

HealthCor was incorporated as a Cayman Islands exempted company on November 18, 2020 for the purpose of effecting a merger, share exchange, asset acquisition, share purchase, reorganization or other similar business combination with one or more businesses. Legacy Hyperfine was incorporated under the laws of the State of Delaware on February 25, 2014 under the name "Hyperfine Research, Inc." On May 25, 2021, the name of Legacy Hyperfine was changed to "Hyperfine, Inc." Liminal was incorporated under the laws of the State of Delaware on September 21, 2018 under the name "EpilepsyCo Inc." On July 20, 2020, the name of Liminal was changed to "Liminal Sciences, Inc." On December 21, 2021, HealthCor changed its jurisdiction of incorporation from the Cayman Islands to the State of Delaware by deregistering as an exempted company in the Cayman Islands and continuing and domesticating as a corporation, incorporated under the laws of the State of Delaware. On December 22, 2021, HealthCor, Legacy Hyperfine and Liminal completed the Business Combination, pursuant to which each of Legacy Hyperfine and Liminal became a wholly owned subsidiary of HealthCor, HealthCor's corporate name was changed to Hyperfine, Inc., Legacy Hyperfine's corporate name was changed to Hyperfine Operations, Inc., Liminal's corporate name was changed to Liminal Operations, Inc. (which was subsequently changed to Liminal Sciences, Inc.), and the business of Legacy Hyperfine and Liminal became the business of the Company. Our principal executive offices are located at 351 New Whitfield Street, Guilford, Connecticut 06437, and our telephone number is (203) 458-7100.

Information Available on the Internet

Our internet address is https://hyperfine.io, to which we regularly post copies of our press releases as well as additional information about us. Our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and all amendments to those reports, will be available to you free of charge through the Investors section of our website as soon as reasonably practicable after such materials have been electronically filed with, or furnished to, the Securities and Exchange Commission (the "SEC"). The SEC maintains an internet site (http://www.sec.gov) that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. We include our web site address in this report only as an inactive textual reference. Information contained in our website does not constitute a part of this report or our other filings with the SEC.

Item 1A. RISK FACTORS

Except for the historical information contained herein, this report contains forward-looking statements that involve risks and uncertainties. These statements include projections about our finances, plans and objectives for the future, future operating and economic performance and other statements regarding future performance. These statements are not guarantees of future performance or events. Our actual results could differ materially from those discussed in this report. Factors that could cause or contribute to these differences include, but are not limited to, those discussed in the following section, as well as those discussed in Part II, Item 7 entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere throughout this report.

You should consider carefully the following risk factors, together with all of the other information included in this report. If any of the following risks, either alone or taken together, or other risks not presently known to us or that we currently believe to not be significant, develop into actual events, then our business, financial condition, results of operations or prospects could be materially adversely affected. If that happens, the market price of our common stock could decline, and stockholders may lose all or part of their investment.

Unless the context otherwise requires, references in this section to "we," "us," "our" and the "Company" refer to Hyperfine, Inc. and its subsidiaries following the Business Combination, or to Legacy Hyperfine, Liminal, or HealthCor prior to the Business Combination, as the case may be.

Risks Related to Our Financial Condition and Capital Requirements

We are an early-stage life sciences technology company with a history of net losses, which we expect to continue, and we may not be able to generate meaningful revenues or achieve and sustain profitability in the future.

We are an early-stage life sciences technology company, and have incurred significant losses since Legacy Hyperfine and Liminal formed in 2014 and 2018, respectively, and expect to continue to incur losses in the future. We incurred net losses of $73.2 million and $64.9 million for the years ended December 31, 2022 and 2021, respectively. As of December 31, 2022, we had an accumulated deficit of $209.5 million. These losses and accumulated deficit were primarily due to the substantial investments made to develop and improve our technology and products. Over the next several years, we expect to continue to devote substantially all of our resources towards continuing development and commercialization of our products and research and development efforts for additional products. These efforts may prove more costly than we currently anticipate. We are generating product revenue but may never generate revenue sufficient to offset our expenses, or at all. In addition, as a public company, we will continue to incur significant legal, accounting, administrative, insurance and other expenses that we did not incur as a private company. Accordingly, we cannot assure you that we will achieve profitability in the future or that, if we become profitable, will sustain profitability.

We have a limited operating history, which may make it difficult to evaluate the prospects for our future viability and predict our future performance. As such, you cannot rely upon our historical operating performance to make an investment or voting decision regarding us.

We have generated limited revenue from the sale of our products and services to date and have incurred significant losses. Our prospects must be considered in light of the uncertainties, risks, expenses, and difficulties frequently encountered by companies in their early stages of operations. We have not yet achieved wide market acceptance for our products, produced our products at scale, refined our sales model, or conducted at scale sales and marketing activities necessary for successful mass product adoption. Consequently, predictions about our future success or viability are highly uncertain and may not be as accurate as they could be if we had a longer operating history or a company history of successfully developing and commercializing products.

In addition, as a business with a limited operating history, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown obstacles. We will need to transition from a company in the early commercialization stage to large scale commercialization, and we may not be successful in such a transition. We have encountered in the past, and will encounter in the future, risks and uncertainties frequently experienced by growing companies with limited operating histories in emerging and rapidly changing industries. If our assumptions regarding these risks and uncertainties, which we will use to plan and operate our business, are incorrect or change, or if we do not address these risks successfully, our results of operations could differ materially from our expectations, and our business, financial condition and results of operations could be adversely affected.

We may need to raise additional capital to fund commercialization plans for our products, including manufacturing, sales and marketing activities, expand our investments in research and development, and commercialize new products and applications.

Our operations have consumed substantial amounts of cash since inception. We expect to use our cash resources to develop and further commercialize our products, develop new products, and for working capital and general corporate purposes. We may require additional capital to further develop and commercialize our products and to develop new products. In addition, our operating plans may change as a result of many factors that may currently be unknown to us, and we may need to seek additional funds sooner than planned.

We cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. Moreover, the terms of any future financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our Class A common stock to decline. The incurrence of indebtedness could result in increased fixed payment obligations, and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek funds through arrangements with collaborative partners or otherwise at an earlier stage than otherwise would be desirable, and we may be required to relinquish rights to some of our technologies or products or otherwise agree to terms that are unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects. In addition, raising additional capital through the issuance of equity or convertible debt securities would cause dilution to holders of our equity securities, and may affect the rights of then-existing holders of our equity securities. Even if we believe that we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or if we have specific strategic considerations.

Our operating results may fluctuate significantly in the future, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or any guidance we may provide.

Our quarterly and annual operating results may fluctuate significantly, which makes it difficult for us to predict our future operating results. These fluctuations may occur due to a variety of factors, many of which are outside our control, including, but not limited to:

- the timing and amount of expenditures that we may incur to develop, commercialize or acquire additional products and technologies or for other purposes, such as the expansion of our sales team and our facilities;
- changes affecting our customers that impact budgets or budget cycles;
- pricing actions, such as the pricing adjustments we made to our subscription plus ownership model during the first quarter of 2022 and during the first quarter of 2023 in which we increased the price of the device while lowering the price of the monthly subscription;
- seasonal spending patterns of our customers;
- the timing of when we recognize any revenues;
- future accounting pronouncements or changes in our accounting policies;
- the outcome of any future litigation or governmental investigations involving the Company, our industry or both;
- higher than anticipated service, replacement and warranty costs;
- the impact of the COVID-19 pandemic on the economy, investment in the life sciences and medical technology industries, our business operations, and resources and operations of our suppliers, future distributors and current and potential customers;

- the impact of political instability and military conflict, such as the conflict in Ukraine, which has resulted in instability in the global financial markets and export controls, and which has contributed to the increased cost of the magnet that is a key custom-made component in our Swoop® system and is manufactured by a single source supplier in Europe, and could result in further supply impacts on our business and have a material adverse impact on our sales in affected markets; and

- general industry, economic and market conditions and other factors, including factors unrelated to our operating performances or the operating performance of our competitors.

The cumulative effects of the factors discussed above could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful.

This variability and unpredictability could also result in us failing to meet the expectations of industry or financial analysts or investors for any period. If we are unable to further commercialize products or generate revenue, or if our operating results fall below the expectations of analysts or investors or below any guidance we may provide, or if the guidance we provide is below the expectations of analysts or investors, the market price of our Class A common stock could decline.

We maintain our cash at financial institutions, often in balances that exceed federally insured limits.

The majority of our cash is held in accounts at U.S. banking institutions that we believe are of high quality. Cash held in non-interest-bearing and interest-bearing operating accounts may exceed the Federal Deposit Insurance Corporation ("FDIC") insurance limits. If such banking institutions were to fail, we could lose all or a portion of those amounts held in excess of such insurance limitations. While the FDIC took control of one such banking institution, Silicon Valley Bank ("SVB"), on March 10, 2023, and the FDIC also took control of Signature Bank ("Signature Bank") on March 12, 2023, we did not have any accounts with SVB or Signature Bank and therefore did not experience any specific risk of loss. The FDIC also announced that account holders would be made whole. Thus, we do not view the risk as material to our financial condition. However, as the FDIC continues to address the situation with SVB, Signature Bank and other similarly situated banking institutions, the risk of loss in excess of insurance limitations has generally increased. Any material loss that we may experience in the future could have an adverse effect on our ability to pay our operational expenses or make other payments and may require us to move our accounts to other banks, which could cause a temporary delay in making payments to our vendors and employees and cause other operational inconveniences.

Risks Related to Our Businesses

Our success depends upon market acceptance of our products and services, our ability to develop and commercialize existing and new products and services and generate revenues, and our ability to identify new markets for our technology.

We have developed, and are engaged in the development of, MRI solutions and non-invasive neural monitoring technology. We are commercializing our Swoop® system to address limitations of current imaging technologies. Our success will depend on the acceptance of our products and services in the U.S. and international healthcare markets. The marketplace may not be receptive to our products and services over competing products, including conventional MRI systems used in hospitals, imaging centers and physicians' offices, and we may be unable to compete effectively. Factors that could affect our ability to successfully further commercialize our current products and services and to commercialize any potential future products and services include:

- challenges of developing (or acquiring externally-developed) technology solutions that are adequate and competitive in meeting the requirements of next-generation design challenges; and

- dependence upon physicians' and other healthcare practitioners' acceptance of our products.

We cannot assure investors that our current products and services or any future products and services will gain broad market acceptance. If the market for our current products and services or any future products and services fails to develop or develops more slowly than expected, or if any of our products or services do not achieve or sustain market acceptance, our business and operating results would be materially and adversely affected.

Medical device development is costly and involves continual technological change, which may render our current or future products obsolete.

The market for point-of-care medical devices is characterized by rapid technological change, medical advances and evolving industry standards. Any one of these factors could reduce the demand for our devices or services or require substantial resources and expenditures for research, design and development to avoid technological or market obsolescence.

Our success will depend on our ability to enhance our current technology, products and services and develop or acquire and market new technologies to keep pace with technological developments and evolving industry standards, while responding to changes in customer needs. A failure to adequately develop or acquire device enhancements or new devices that will address changing

technologies and customer requirements adequately, or to introduce such devices on a timely basis, may have a material adverse effect on our business, financial condition and results of operations.

We might have insufficient financial resources to improve existing devices, advance technologies and develop new devices at competitive prices. Technological advances by one or more competitors or future entrants into the field may result in our current devices becoming non-competitive or obsolete, which may decrease revenues and profits and adversely affect our business and results of operations.

We may encounter significant competition across our existing and future planned products and services and in each market in which we sell or plan to sell our products and services from various companies, many of which have greater financial and marketing resources than us. Our primary competitors include several large companies which currently dominate the medical imaging market, including General Electric, Siemens, Philips, Hologic, Varian, Fuji, Toshiba, Canon and Hitachi.

In addition, our competitors, some of which are well-established manufacturers with significant resources, may engage in aggressive marketing tactics. Competitors may also possess the ability to commercialize additional lines of products, bundle products or offer higher discounts and incentives to customers in order to gain a competitive advantage. If the prices of competing products are lowered as a result, we may not be able to compete effectively.

We will be dependent upon the success of our sales and customer acquisition and retention strategies.

Our business is dependent upon the success of our sales and customer acquisition and retention strategies, and our marketing efforts are focused on developing a strong reputation with healthcare providers and increasing awareness of our products and services. If we fail to maintain a high quality of service or a high quality of device technology, we may fail to retain existing users or add new users. If we do not successfully continue our sales efforts and promotional activities, particularly to health systems and large institutions, or if existing users decrease their level of engagement, our revenue, financial results and business may be significantly harmed. Our future success depends upon continued expansion of our commercial operations in the United States and internationally, as well as entering additional markets to commercialize our products and services. We believe that our growth will depend on the further development and commercialization of our current products and services, regulatory authorization of our current products and services in additional markets, and development, regulatory authorization and commercialization of our future products and services. If we fail to expand the use of our products and services in a timely manner, we may not be able to expand our market share or to grow our revenue. Our financial performance will be substantially dictated by our success in adding, retaining and engaging active users of our products. If customers do not perceive our products or services to be useful, reliable and trustworthy, we may not be able to attract or retain customers or otherwise maintain or increase the frequency and duration of their engagement. As our business model is predicated on device hardware sales, software subscriptions, and subscriptions for use of device hardware and software, there is risk that any decline in sales, subscriptions and subscription renewal rates will adversely impact our business. A decrease in customer retention, growth or engagement with our products and services may have a material and adverse impact on our revenue, business, financial condition and results of operations.

Any number of factors could negatively affect customer retention, growth and engagement, including:

- customers choosing competing products or choosing to use conventional MRI systems over our products;
- failure to introduce new and improved products and services;
- inability to continue to develop products that customers find effective and that achieve a high level of market acceptance;
- changes in customer sentiment about the quality or usefulness of our products and services or concerns related to safety, security, privacy and data sharing or other factors;

- adverse changes in our products that are mandated by legislation or regulatory agencies, both in the United States and internationally; or
- technical or other problems preventing us from delivering products or services in a rapid and reliable manner or otherwise affecting the user experience.

We expect to generate an increasing portion of our revenue internationally in the future and may become subject to various additional risks relating to our international activities, which could adversely affect our business, operating results and financial condition.

Revenue from non-U.S. countries was 37% of total revenue for the year ended December 31, 2022. We believe that an increasing percentage of our future revenue will come from international sources as we continue to commercialize our products and services in the United Kingdom, Canada, Australia, New Zealand and Pakistan, and have received CE marking in the European Union, we seek regulatory authorization for our products in additional jurisdictions, and we seek to expand our sales and marketing opportunities internationally. Our success will depend, in part, upon our ability to succeed in differing legal, regulatory, economic, social and political conditions by developing, implementing and maintaining policies and strategies that are effective in each location where we do business. We have limited experience operating internationally and engaging in international business involves a number of difficulties and risks, including:

- the challenges associated with building local brand awareness, obtaining local key opinion leader support and clinical support, implementing reimbursement strategies and building local marketing and sales teams;
- required compliance with foreign regulatory requirements and laws, including regulations and laws relating to patient data and medical devices;
- trade relations among the United States and those foreign countries in which our current or future customers, distributors, manufacturers and suppliers have operations, including protectionist measures such as tariffs and import or export licensing requirements, whether imposed by the United States or such foreign countries, such as China;
- difficulties and costs of staffing and managing foreign operations;
- difficulties protecting, procuring or enforcing intellectual property rights internationally;
- required compliance with anti-bribery laws, such as the U.S. Foreign Corrupt Practices Act, data privacy requirements, labor laws and anti-competition regulations;
- laws and business practices that may favor local companies;
- longer payment cycles and difficulties in enforcing agreements and collecting receivables through certain foreign legal systems;
- political and economic instability; and
- potentially adverse tax consequences, tariffs, customs charges, bureaucratic requirements and other trade barriers.

For example, our business may continue to be impacted by the conflict in Ukraine, any economic or other sanctions imposed on Russia and others for aggression in Ukraine, and any economic or other countermeasures by affected countries. Any such conflict may also impact our ability to secure raw materials and finished products and create supply chain disruptions. For example, we have incurred increased costs of the magnet, a key custom-made component in our Swoop® system, which is manufactured by a single source supplier in Europe. In the event of further increased costs or interruption from any of our suppliers or manufacturers, we may not be able to obtain capacity from other sources or develop alternate or secondary sources without incurring material additional costs and substantial delays. As we seek to expand into international markets, the conflict in Ukraine and any related economic or other sanctions or related countermeasures could limit our ability to expand our business and have a material adverse impact on demand for our products and sales in affected markets. In addition, sanctions imposed on Russia and others in response to such conflict may also continue to adversely impact the financial markets and the global economy, and any economic countermeasures by Russia and others could exacerbate market and economic instability.

If we dedicate significant resources to our international operations and are unable to manage these risks effectively, our business, operating results and financial condition may be adversely affected.

We are subject to export and import control laws and regulations that could impair our ability to compete in international markets or subject us to liability if we violate such laws and regulations.

We are required to comply with export and import control laws, which may affect our ability to enter into or complete transactions with certain customers, business partners, and other persons. In certain circumstances, export control regulations may prohibit the export of certain products, services, and technologies. We may be required to obtain an export license before exporting a controlled item, and granting of a required license cannot be assured. Compliance with the import laws that apply to our businesses may restrict our access to, and may increase the cost of obtaining, certain products and could interrupt our supply of imported inventory.

Exported technologies necessary to develop and manufacture certain products are subject to U.S. export control laws and similar laws of other jurisdictions. We may be subject to adverse regulatory consequences, including government oversight of facilities and export transactions, monetary penalties, and other sanctions for violations of these laws. In certain instances, these regulations may prohibit us from developing or manufacturing certain of our products for specific applications outside the United States. Failure to comply with any of these laws and regulations could result in civil and criminal, monetary, and nonmonetary penalties; disruptions to our business; limitations on our ability to import and export products and services; or damage to our reputation.

If we experience decreasing prices for our products and are unable to reduce our expenses, including the per unit cost of producing our products, there may be a material adverse effect on our business, results of operations, financial condition and cash flows.

We may experience decreasing prices for our products due to pricing pressure from managed care organizations and other third-party payors and suppliers, increased market power of our payors as the medical device industry consolidates, and increased competition among suppliers, including manufacturing services providers. If the prices for our products and services decrease and we are unable to reduce our expenses, including the cost of sourcing materials, logistics and the cost to manufacture our products, our business, results of operations, financial condition and cash flows may be adversely affected. To the extent that we engage in enterprise sales, we may be subject to procurement discounts, which could have a negative impact on the prices of our products.

We are undertaking internal restructuring activities that could result in disruptions to our business or otherwise materially harm our results of operations or financial condition.

In December 2022, we announced that we committed to an organizational restructuring designed to decrease our costs and create a more streamlined organization to support our business. As a result, we terminated approximately 13% of our global workforce including, among others, the employees of our subsidiary, Liminal. We believe this re-prioritized strategic focus is the best way to optimize our financial and other resources to advance our goal of developing and commercializing our products and services. There can be no assurance that our restructuring will achieve the cost savings, operating efficiencies or other benefits that we may initially expect. Restructuring activities may also result in a loss of continuity, accumulated knowledge and inefficiency during transitional periods and thereafter. In addition, internal restructurings can require a significant amount of time and focus from management and other employees, which may divert attention from operations. Further, our restructuring may result in unexpected expenses or liabilities and/or write-offs. If our restructuring fails to achieve some or all of the expected benefits therefrom, our cash resources may not last as long as estimated and our business, results of operations and financial condition could be materially and adversely affected.

If we are unable to attract, recruit, train, retain, motivate and integrate key personnel and expand our organization, our operations may be disrupted and we may not achieve our goals.

Our future success depends on our ability to attract, recruit, train, retain, motivate and integrate key personnel, including our Vice Chairperson and the Founder of Legacy Hyperfine and Liminal, Dr. Jonathan Rothberg, our Executive Chairperson, R. Scott Huennekens, and our President and Chief Executive Officer, Maria Sainz, as well as other members of our management team and our research and development, manufacturing, software engineering and sales and marketing personnel. As our development and commercialization plans and strategies develop, we will need additional managerial, operational, sales, marketing, financial, legal and other resources. Competition for qualified personnel in the medical device industry is intense. Due to this intense competition, we may be unable to attract and retain the qualified personnel necessary for the development of our business or to recruit suitable replacement personnel.

Additionally, in December 2022, we announced that we committed to an organizational restructuring designed to decrease our costs and create a more streamlined organization to support our business. As a result, we terminated approximately 13% of our global workforce including, among others, the employees of our subsidiary, Liminal. While we have confidence in our remaining team, including the board of directors, the restructuring may cause concerns from third parties with whom we do business and may increase the likelihood of turnover of other key employees.

We believe that our management team must be able to act decisively to apply and adapt our business model in the rapidly changing markets in which we compete. In addition, we rely upon technical and scientific employees or third-party contractors to effectively establish, manage and grow our business. Consequently, we believe that our future viability will depend largely on our ability to attract and retain highly skilled managerial, sales, scientific and technical personnel. In order to do so, we may need to pay higher compensation or fees to our employees or consultants than we currently expect, and such higher compensation payments may have a

negative effect on our operating results. Competition for experienced, high-quality personnel is intense, and we cannot assure investors that we will be able to recruit and retain such personnel. Our growth depends, in particular, on attracting and retaining highly-trained sales personnel with the necessary technical background and ability to understand our products and services at a technical level to effectively identify and sell to potential new customers and develop new products. Because of the technical nature of our products and the dynamic market in which we compete, any failure to attract, recruit, train, retain, motivate and integrate qualified personnel could materially harm our operating results and growth prospects.

Our management may need to divert a disproportionate amount of our attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of additional products. If our management is unable to effectively manage our growth, our expenses may increase more than expected. Our ability to generate and/or grow revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize products and services and compete effectively will depend, in part, on our ability to effectively manage any future growth.

We have limited experience in marketing and selling our products and related services, and if we are unable to successfully commercialize our products and related services, our business and operating results will be adversely affected.

We have limited experience marketing and selling our products and related services. We began selling our Swoop® system in 2020 and currently sell the device directly to customers through direct sales. Future sales of our products will depend in large part on our ability to effectively market and sell our products and services, successfully manage and expand our sales force, and increase the scope of our marketing efforts. We have entered into distribution arrangements and may enter into additional distribution arrangements in the future. Because we have limited experience in marketing and selling our products, our ability to forecast demand, the infrastructure required to support such demand and the sales cycle to customers is unproven. If we do not build an efficient and effective marketing and sales force, our business and operating results will be adversely affected.

We rely on a single contract manufacturer, Benchmark Electronics, Inc. ("Benchmark"), to test, assemble and supply our finished products. If Benchmark fails to fulfill its obligations under its existing contractual arrangements with us or does not perform satisfactorily, our ability to source our devices could be negatively and adversely affected.

In October 2018, Legacy Hyperfine entered into a Manufacture and Supply Agreement with Benchmark (the "MSA"). Under the MSA, Benchmark agreed to manufacture our products pursuant to binding purchase orders. The parties have agreed to meet periodically regarding any minimum order quantities of components under the MSA. We also have certain inventory related obligations, including the obligation to purchase excess and obsolete components from Benchmark. See *"Item 1. Business - Key Agreements - Manufacture and Supply Agreement with Benchmark Electronics, Inc."*

In the event it becomes necessary to utilize a different contract manufacturer for our component products, we would experience additional costs, delays and difficulties in obtaining such components as a result of identifying and entering into an agreement with a new contract manufacturer as well as preparing such new manufacturer to meet the logistical requirements associated with manufacturing our devices, and our business would suffer.

We rely on a limited number of suppliers for our products. A loss of any of these suppliers could negatively affect our business.

We rely on a limited number of suppliers to manufacture components for our products, including in some cases only a single supplier for some of our components. In addition, we rely on Benchmark to purchase the magnet used in our Swoop® system, which is a key custom-made component manufactured by a single source supplier in Europe. Our reliance on a limited number of suppliers increases our risks, since we do not currently have alternative or replacement suppliers beyond these key parties. In the event of interruption from any of our suppliers, we may not be able to increase capacity from other sources or develop alternate or secondary sources without incurring material additional costs and substantial delays.

If we experience a significant increase in demand for our products, or if we need to replace an existing supplier or manufacturer, we may be unable to supplement or replace them on terms that are acceptable to us, which may undermine our ability to deliver our products to customers in a timely manner. Identifying suitable suppliers and manufacturers is an extensive process that requires us to become satisfied with their quality control, technical capabilities, responsiveness and service, financial stability, regulatory compliance, and labor and other ethical practices. Accordingly, a loss of any of our suppliers or our device manufacturer could have an adverse effect on our business, financial condition and operating results.

Pricing pressures from contract suppliers or manufacturers on which we rely may impose pricing pressures.

Third-party suppliers utilized by our manufacturer such as Benchmark have and may continue to impose pricing pressures. Because we currently also rely on Benchmark to manufacture, test and ship all of the Swoop® systems and on a limited number of suppliers to supply our components, including Benchmark to purchase the magnet used in the scanner from a single source supplier, such pricing pressures from a third party such as Benchmark have and could increase our costs and could force us to increase the prices of our products if we are unable to enter into alternative arrangements with other suppliers or manufacturers, potentially leading to decreased customer demand.

If we do not successfully optimize and operate our sales and potential future distribution channels or we do not effectively expand and update our infrastructure, our operating results and customer experience may be negatively impacted.

If we do not adequately predict market demand or otherwise optimize and operate our sales and potential future distribution channels successfully, it could result in excess or insufficient inventory or fulfillment capacity, increased costs, or immediate shortages in product or component supply, or harm our business in other ways. In addition, if we do not maintain adequate infrastructure to enable us to, among other things, manage our purchasing and inventory, it could negatively impact our operating results and customer experience.

The market for our products and services is new, rapidly evolving, and increasingly competitive, as the healthcare industry in the United States is undergoing significant structural change, which makes it difficult to forecast demand for our products and services.

The market for our products and services is new and rapidly evolving, and it is uncertain whether we will achieve and sustain high levels of demand and market adoption. Our future financial performance will depend in part on growth in this market and on our ability to adapt to the changing demands of customers. It is difficult to predict the future growth rate and size of our target market. As a result, our commercial expectations may not be achieved. Negative publicity concerning our products could limit market acceptance of our products and services. If our customers do not perceive the benefits of our products and services, or if our products and services do not attract new customers, then our market may not develop at all, or we may develop more slowly than we expect. Our success will depend to a substantial extent on the willingness of healthcare organizations to increase their use of our technology and our ability to demonstrate the value of our technology relative to competing products and services to existing and potential customers. If healthcare organizations do not recognize or acknowledge the benefits of our products and services or if we are unable to reduce healthcare costs or drive positive health outcomes, then the market for our solutions might not develop at all, or might develop more slowly than we expect. Similarly, negative publicity regarding patient confidentiality and privacy in the context of technology-enabled healthcare or concerns experienced by competitors could limit market acceptance of our products and services.

The healthcare industry in the United States is undergoing significant structural change and is rapidly evolving. Our products and services are offered on a subscription basis, and the adoption of subscription business models is still relatively new, especially in the healthcare industry. If companies do not shift to subscription business models and subscription health management tools do not achieve widespread adoption, or if there is a reduction in demand for subscription products and services or subscription health management tools, our business, financial condition, and results of operations could be adversely affected.

Quality problems could lead to recalls or safety alerts and/or reputational harm and could have a material adverse effect on our business, results of operations, financial condition and cash flows.

Quality of our products is very important to us and our customers due to the serious and costly consequences of product failure. Our business exposes us to potential product liability risks that are inherent in the design, manufacture, and marketing of medical devices. Product or component failures, manufacturing nonconformities, design defects, off-label use, or inadequate disclosure of product-related risks or product-related information with respect to our products, if they were to occur, could result in inaccurate imaging and safety risks. These problems could lead to the recall of, or the issuance of a safety alert relating to, our products, and could result in product liability claims and lawsuits.

Additionally, the manufacture and production of our products must occur in a highly controlled and clean environment to minimize particles and other yield- and quality-limiting contaminants. Weaknesses in process control or minute impurities in materials may cause defective products. If we are not able to maintain stringent quality controls, or if contamination problems arise, our development and commercialization efforts could be delayed, which would harm our business and results of operations.

If we fail to meet any applicable product quality standards and our products are the subject of recalls or safety alerts, our reputation could be damaged, we could lose customers, and our revenue and results of operations could decline.

If we are not able to develop and release new products and services, or successful enhancements, new features and modifications to our existing products and services, to successfully implement our software subscription solutions or to achieve adequate clinical utility, our business, financial condition and results of operations could be adversely affected.

The markets in which we operate are characterized by rapid technological change, frequent new product and service introductions and enhancements, changing customer demands, and evolving industry standards. The introduction of products and services embodying new technologies can quickly make existing products and services, including software subscriptions, obsolete and unmarketable. Additionally, changes in laws and regulations could impact the usefulness of our products and could necessitate changes or modifications to our products to accommodate such changes. We invest substantial resources in researching and developing new products and enhancing existing products by incorporating additional features, improving functionality, and adding other improvements to meet customers' evolving needs. The success of any enhancements or improvements to our existing products or any new products depends on several factors, including timely completion, competitive pricing, adequate quality testing, integration with new and existing technologies and third-party partners' technologies and overall market acceptance. We may not succeed in developing, marketing and delivering on a timely and cost-effective basis enhancements or improvements to our existing products or any new products that respond to continued changes in market demands or new customer requirements, and any enhancements or improvements to our products or any new solutions may not achieve market acceptance. Since developing our products is complex, the timetable for the release of new products and enhancements to existing products is difficult to predict, and we may not offer new products and updates as rapidly as our customers require or expect. Any new products that we develop may not be introduced in a timely or cost-effective manner, may contain errors or defects, or may not achieve the broad market acceptance necessary to generate sufficient revenue. Moreover, even if we introduce new products, we may experience a decline in revenue from our existing products that is not offset by revenue from the new products. For example, customers may delay making purchases of new products to permit them to make a more thorough evaluation of these products or until industry and marketplace reviews become widely available. Customers may also delay purchasing a new product because their existing product or other device continues to meet their needs. Some customers may hesitate to migrate to a new product due to concerns regarding the performance of the new product. In addition, we may lose existing customers who choose a competitor's products and services. This could result in a temporary or permanent revenue shortfall and adversely affect our business, financial condition and results of operations.

The introduction of new products and solutions by competitors, the development of entirely new technologies to replace existing offerings or shifts in healthcare benefits trends could make our products obsolete or adversely affect our business, financial condition and results of operations. We may experience difficulties with software development, industry standards, design or marketing that could delay or prevent our development, introduction or implementation of new products, enhancements, additional features or capabilities. If customers do not widely purchase and adopt our products, we may not be able to realize a return on our investment. If we do not accurately anticipate customer demand or if we are unable to develop, license or acquire new features and capabilities on a timely and cost-effective basis, or if such enhancements do not achieve market acceptance, it could result in adverse publicity, loss of revenue or market acceptance or claims by customers brought against us, each of which could have a material and adverse effect on our reputation, business, results of operations and financial condition.

We are party to Technology and Services Exchange Agreements with certain affiliated companies, pursuant to which the parties agreed to share personnel and certain non-core technologies. The sharing arrangements under the agreements may prevent us from fully utilizing our personnel and/or the technologies shared under the agreements. Furthermore, if these agreements were to terminate, or if we were to lose access to these technologies and services, our business could be adversely affected.

We entered into Technology and Services Exchange Agreements (each, a "TSEA" and collectively, the "TSEA") with other participant companies controlled by the Rothbergs. A TSEA by and among Butterfly Network, Inc., AI Therapeutics, Inc., Quantum-Si Incorporated, 4Bionics, identifeye HEALTH Inc. (f/k/a Tesseract Health, Inc.), Detect, Inc. (f/k/a Homodeus Inc.), Legacy Hyperfine and Liminal was signed in November 2020; a TSEA by and among Quantum-Si Incorporated, AI Therapeutics, Inc., 4Bionics, identifeye HEALTH Inc., Detect, Inc., Legacy Hyperfine and Liminal was signed in February 2021 (and which Protein Evolution, Inc. joined in August 2021); and a TSEA by and among Legacy Hyperfine, Liminal, AI Therapeutics, Inc., identifeye HEALTH Inc. and Detect, Inc. was signed in July 2021 and became effective upon the Closing. Under the TSEA, we and the other participant companies may, in their discretion, permit the use of certain non-core technologies, which include any technologies, information or equipment owned or otherwise controlled by the participant company that are not specifically related to the core business area of the participant, such as software, hardware, electronics, fabrication and supplier information, vendor lists and contractor lists, with the other participant companies. The TSEA provides that ownership of each non-core technology shared by us or another participant company will remain with the company that originally shared the non-core technology. In addition, any participant company (including us) may, in its discretion, permit its personnel to be engaged by another participant company to perform professional, technical or consulting services for such participant. Unless otherwise agreed to by us and the other participant company, all rights, title and interest in and to any inventions, works-of-authorship, idea, data or know-how invented, made, created or developed by the personnel (employees, contractors or consultants) in the course of conducting services for a participant company ("Created IP") will be owned by the participant company for which the work was performed, and the recipient participant company grants to the party that had its personnel provide the services that resulted in the creation of the Created IP a royalty-free, perpetual, limited, worldwide, non-exclusive, sub-licensable (and with respect to software, sub-licensable in object code only) license to utilize the Created IP only in the core business field of the originating participant company, including a license to create and use derivative works based on the Created IP in the originating participant's core business field, subject to any agreed upon restrictions.

The technology and personnel-sharing arrangements under the TSEA may prevent us from fully utilizing our personnel if such personnel are also being used by the other participant companies and may also cause our personnel to enter into agreements with or provide services to other companies that interfere with their obligations to us. Created IP under the TSEA may be relevant to our business and created by our personnel but owned by the other participant companies. Furthermore, if the TSEA were to terminate, or if we were to lose access to the technologies and services available pursuant to the TSEA, our business could be adversely affected.

We may acquire other companies or technologies, which could fail to result in a commercial product or net sales, divert our management's attention, result in additional dilution to our stockholders and otherwise disrupt our operations and harm our operating results.

We may in the future seek to acquire or invest in businesses, applications or technologies that we believe could complement or expand our portfolio, enhance our technical capabilities or otherwise offer growth opportunities. However, we cannot assure you that we would be able to successfully complete any acquisition we choose to pursue, or that we would be able to successfully integrate any acquired business, product or technology in a cost-effective and non-disruptive manner. The pursuit of potential acquisitions may divert the attention of management and cause us to incur various costs and expenses in identifying, investigating and pursuing suitable acquisitions, whether or not they are consummated. We may not be able to identify desirable acquisition targets or be successful in entering into an agreement with any particular target or obtain the expected benefits of any acquisition or investment.

To date, the growth of our operations has been largely organic, and we have limited experience in acquiring other businesses or technologies. We may not be able to successfully integrate any acquired personnel, operations and technologies, or effectively manage the combined business following an acquisition. Acquisitions could also result in dilutive issuances of equity securities, the use of our available cash, or the incurrence of debt, which could harm our operating results. In addition, if an acquired business fails to meet our expectations, our operating results, business and financial condition may suffer.

As international expansion of our business occurs, it will expose us to market, regulatory, political, operational, financial and economic risks associated with doing business outside of the United States.

Our long term strategy is to increase our international presence. We have received regulatory authorization in the European Union, the United Kingdom, Canada, Australia, New Zealand and Pakistan. This strategy may include establishing and maintaining physician outreach and education capabilities outside of the United States and expanding our relationships with international customers. Doing business internationally involves a number of risks, including:

- Difficulties in staffing and managing our international operations;
- Multiple, conflicting and changing laws and regulations such as tax laws, privacy laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses;
- Reduced or varied protection for intellectual property rights in some countries;
- Obtaining regulatory clearance where required for our products in various countries;
- Requirements to maintain data and the processing of that data on servers located within such countries;
- Limits on our ability to penetrate international markets if we are required to manufacture our products locally;
- Financial risks, such as longer payment cycles, difficulty collecting accounts receivable, foreign tax laws and complexities of foreign value-added tax systems, the effect of local and regional financial pressures on demand and payment for our products and exposure to foreign currency exchange rate fluctuations;
- Restrictions on the site-of-service for use of our products and the economics related thereto for physicians and other healthcare practitioners;
- Natural disasters and economic instability, including outbreak of disease, boycotts, curtailment of trade and other market restrictions;
- Wars, terrorism and political unrest, such as the conflict in Ukraine, which has resulted in instability in the global financial markets and export controls, and which could result in supply disruptions for us, including because one key custom-made component in our Swoop® system is the magnet, which is manufactured by a single source supplier in Europe, and which could also have a material adverse impact on our sales in affected markets; and
- Regulatory and compliance risks that relate to maintaining accurate information and control over activities subject to regulation under the U.S. Foreign Corrupt Practices Act, and comparable laws and regulations in other countries.

Any of these factors could significantly harm our future international expansion and operations and, consequently, have a material adverse effect on our business, financial condition and results of operations.

The COVID-19 pandemic has and could continue to negatively affect various aspects of our business, make it more difficult for us to meet our obligations to our customers, and result in reduced demand for our products and services, which could have a material adverse effect on our business, financial condition, results of operations, or cash flows.

In March 2020, the World Health Organization declared the global outbreak of COVID-19 to be a pandemic. We continue to closely monitor the recent COVID-19 developments, including the lifting of COVID-19 safety measures, the drop in COVID-19 vaccination rates, the implementation of, and reaction to, vaccine mandates, the spread of new strains or variants of the coronavirus, and supply chain and labor shortages. The COVID-19 pandemic has had, and is expected to continue to have, an adverse impact on our operations. COVID-19 created multiple commercial challenges in 2022 and 2021 and commercial challenges and restrictions from COVID-19 have been generally reduced in 2023. We experienced restrictions on our salesforce's ability to visit sites during 2022. During second half of 2022, hospitals and other healthcare providers started to ease restrictions and our salesforce's ability to visit sites improved. Commercially, many hospitals and other healthcare providers decreased spending and limited physical access to facilities, slowing our ability to demonstrate our Swoop® system. In addition, many hospitals and other healthcare providers continue to focus their attention on addressing COVID-19, which we believe has resulted in lower sales volume. Trade shows and conferences moved to a virtual platform creating difficulty in demonstrating our device to key stakeholders. It was not uncommon to host virtual product demonstrations with 6-10 physicians, something that would ordinarily not happen or would take many weeks of planning to produce. While physician society conferences are beginning to ramp, attendance has remained below pre-pandemic levels. As such we continue to supplement the conferences with "Demo at Your Door" — demonstrations providing target customers hands-on device experience at a place of their choosing. Virtual demonstrations, even though they generated a lot of interest in our product, often did not result in sales, and all sales required an in-person product demonstration. As more conferences begin to be held in-person, we expect to improve our ability to provide product demonstrations to potential customers. It is unclear whether or not conferences will have the same in-person attendance as they would have had in the past.

Because the manufacturing of our Swoop® system was developed, and our commercial launch of our Swoop® system occurred, during the COVID-19 pandemic market and manufacturing conditions, we did not have to materially adjust our existing resource allocation or our factors of production because of the COVID-19 pandemic. However, if there are further waves of the COVID-19 pandemic, we may experience a greater negative impact in our supply chain than we have previously. During the COVID-19 pandemic and the variants that followed, our suppliers agreed to shift new work to domestic suppliers to help reduce the risk of manufacturing delays. Our supplier and sub tier suppliers have been adversely affected by COVID-19 and the supply of certain components and raw materials used in our product has been and may continue to be slowed as a direct result of COVID-19 and its variants. Any disruption in the operations of our employees, suppliers, customers, manufacturers or access to customers would likely impact our sales and operating results. We have also experienced increases in product costs as raw materials have been constrained. Prices have risen sharply over the past year, and lead times have extended dramatically, particularly on semiconductor products. Over the next 12 months, we expect prices to increase due to the raw material demand surges across numerous industries, along with labor and transportation related constraints. We also expect lead times to reduce as component production levels recover to meet demand. In addition, future regulatory authorizations by the FDA may take longer because of COVID-19 pandemic-related delays. We are continuing to monitor and assess the effects of the COVID-19 pandemic on our commercial operations. However, we cannot at this time accurately predict what effects these conditions will ultimately have on our operations due to uncertainties relating to variants, the severity of the disease, the duration of the outbreak, and the length of the travel restrictions and business closures imposed by the governments of impacted countries. In addition, the COVID-19 pandemic could continue to adversely affect the economies and financial markets of many countries, which could result in an economic downturn that could affect demand for our products and likely impact our operating results.

Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets, including changes in inflation, interest rates and overall economic conditions and uncertainties. For instance, if inflation or other factors were to significantly increase our business costs, it may not be feasible to pass price increases on to our customers. Inflation could also adversely affect the ability of our customers to purchase our products. An economic downturn, could result in a variety of risks to our business, including weakened demand for our products and our inability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our manufacturers and suppliers, possibly resulting in supply disruption, or cause future customers to delay making payments for our products. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

The enactment of legislation implementing changes in the U.S. Taxation of international business activities, the adoption of other tax reform policies or changes in tax legislation or policies in jurisdictions outside of the United States could materially impact our results of operations and financial condition.

We are subject to income tax in the numerous jurisdictions in which we operate. Reforming the taxation of international businesses has been a priority for politicians, and a wide variety of potential changes have been proposed. Some proposals, several of which have been enacted, impose incremental taxes on gross revenue, regardless of profitability. Furthermore, it is reasonable to expect that global taxing authorities will be reviewing current legislation for potential modifications in reaction to the implementation of the 2017 Tax Cuts and Jobs Act (the "Tax Act") in the United States. Due to the expanding scale of our international business activities, changes in the taxation of such activities may increase our worldwide effective tax rate and the amount of taxes we pay and harm our business.

In the United States, the Tax Act enacted on December 22, 2017 significantly affected U.S. Tax law by changing how the United States imposes income tax on multinational corporations. The U.S. Department of Treasury has broad authority to issue regulations and interpretative guidance that may significantly impact how we will apply the law and impact our results of operations in the period issued.

The Tax Act requires complex computations not previously provided in U.S. Tax law. As such, the application of accounting guidance for such items remains uncertain. Further, compliance with the Tax Act and the accounting for such provisions requires an accumulation of information not previously required or regularly produced. As additional regulatory guidance is issued by the applicable taxing authorities, as accounting treatment is clarified, and as we perform additional analysis on the application of the law, our effective tax rate could be materially different.

U.S. taxation of international business activities or the adoption of tax reform policies could materially impact our future financial position and results of operations.

Limitations on the ability of taxpayers to claim and utilize foreign tax credits and the deferral of certain tax deductions until earnings outside of the United States are repatriated to the United States, as well as changes to U.S. Tax laws that may be enacted in the future, could impact the tax treatment of future foreign earnings. Should the scale of our international business activities expand, any changes in the U.S. taxation of such activities could increase our worldwide effective tax rate and harm our future financial position and results of operations.

We may face exposure to foreign currency exchange rate fluctuations.

While we have historically transacted in U.S. Dollars with the majority of our customers and suppliers, we have transacted in some foreign currencies and may transact in more foreign currencies in the future. Accordingly, changes in the value of foreign currencies relative to the U.S. Dollar may affect our revenue and operating results. As a result of such foreign currency exchange rate fluctuations, it could be more difficult to detect underlying trends in our business and operating results. In addition, to the extent that fluctuations in currency exchange rates cause our operating results to differ from our expectations or the expectations of our investors, the trading price of our stock could be adversely affected.

Our ability to use net operating losses to offset future taxable income may be subject to certain limitations.

As of December 31, 2022, Legacy Hyperfine had federal net operating loss carryforwards ("NOLs") to offset future taxable income of approximately $145 million, of which $12.1 million will begin to expire in 2034 if not utilized. As of December 31, 2022, Liminal had federal NOLs to offset future taxable income of approximately $13.4 million. A lack of future taxable income would adversely affect our ability to utilize these NOLs. In addition, under Section 382 of the Internal Revenue Code of 1986, as amended (the "Code"), a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre-change NOLs and other pre-change tax attributes (such as research tax credits) to offset post-change taxable income. For these purposes, an ownership change generally occurs where the equity ownership of one or more stockholders or groups of stockholders who owns at least 5% of a corporation's stock increases its ownership by more than 50 percentage points over its lowest ownership percentage within a three-year period (calculated on a rolling basis). Our existing NOLs may be subject to limitations arising out of previous ownership changes and we may be limited as to the amount that can be utilized each year as a result of such previous ownership changes, including the Business Combination and related transactions. In addition, future changes in our stock ownership, including future offerings, as well as other changes that may be outside of our control, could result in additional ownership changes under Section 382 of the Code. Our NOLs may also be impaired under similar provisions of state law. We have recorded a full valuation allowance related to our NOLs and other deferred tax assets due to the uncertainty of the ultimate realization of the future benefits of those assets.

In addition to the limitations discussed above under Sections 382 of the Code, the utilization of NOLs incurred in taxable years beginning after December 31, 2017, are subject to limitations adopted by the Tax Cuts and Jobs Act, as modified by the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act"). Under the Tax Act, in general, NOLs generated in taxable years beginning after December 31, 2017 may offset no more than 80 percent of such year's taxable income and there is no ability for such NOLs to be carried back to a prior taxable year. The CARES Act modifies the Tax Act with respect to the Tax Act's limitation on the deduction of NOLs and provides that NOLs arising in taxable years beginning after December 31, 2017 and before January 1, 2021, may be carried back to each of the five taxable years preceding the tax year of such loss, but NOLs arising in taxable years beginning after December 31, 2020 may not be carried back. In addition, the CARES Act eliminates the limitation on the deduction of NOLs to 80 percent of

current year taxable income for taxable years beginning before January 1, 2021. As a result of such limitation, we may be required to pay federal income tax in some future year notwithstanding that we had a net loss for all years in the aggregate.

Risks Related to Healthcare Industry Shifts and Changing Regulations

We are subject to extensive government regulation, which could restrict the development, marketing, sale and distribution of our products and could cause us to incur significant costs.

Our medical devices and associated services are subject to extensive pre-market and post-market regulation by the FDA and various other federal, state, local and foreign government authorities. Government regulation of medical devices is meant to assure their safety and effectiveness, and includes requirements for, among other things:

- design, development and manufacturing processes;
- labeling, content and language of instructions for use and storage;
- product testing, nonclinical studies and clinical trials;
- regulatory clearances and approvals, including pre-market clearance or pre-market approval;
- establishment registration, device listing and ongoing compliance with the QSR requirements;
- advertising and promotion;
- marketing, sales and distribution;
- conformity assessment procedures;
- product traceability and record-keeping procedures;
- review of product complaints, complaint reporting, recalls and field safety corrective actions;
- post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury;
- post-market studies (if applicable); and
- product import and export.

The laws and regulations to which we and our products are subject are complex and subject to periodic changes. Regulatory changes could result in restrictions on our ability to carry on or expand our operations, higher than anticipated costs or lower than anticipated sales.

Before a new medical device, or a significant modification of a medical device, including a new use of or claim for an existing product, can be marketed in the United States, we must first receive either 510(k) clearance or premarket approval ("PMA") from the FDA, unless an exemption applies. In the 510(k) clearance process, the FDA must determine that a proposed device is "substantially equivalent" to a device legally on the market, known as a "predicate" device, with respect to intended use, technology and safety and effectiveness, in order to clear the proposed device for marketing. Clinical data is sometimes required to support substantial equivalence. Legacy Hyperfine received 510(k) clearance from the FDA for its point-of-care MRI system in 2020. In addition, Legacy Hyperfine's proprietary BrainInsight product is a fully automated MR imaging post-processing medical software that is regulated as a picture archiving and communications system, which may include both hardware and software components, and which is classified by FDA as a Class II medical device. BrainInsight received 510(k) marketing clearance in January 2021 for use in automatic labeling, spatial measurement, and volumetric quantification of brain structures from a set of low-field MR images and to return annotated and segmented images, color overlays, and reports. More recently, in November 2021, Legacy Hyperfine received 510(k) clearance for its new advanced image reconstruction technology using deep learning.

We may be required to obtain a new 510(k) clearance or PMA approval for significant post-market modifications to our products, including any modifications made to the commercially marketed our devices. In addition, Liminal does not have any commercial products. In the event Liminal's products are marketed for clinical monitoring or therapeutic uses in the future, they will be regulated by the FDA as medical devices. Because the products remain in the development stage, it is presently unclear what level of risk the agency will assign to such products, what special controls may be imposed on such products (if any), and what regulatory requirements would be applicable to such products.

Obtaining 510(k) clearance or PMA approval for medical devices can be expensive and time-consuming, and entails significant user fees, unless an exemption is available. The FDA's process for obtaining 510(k) clearance usually takes three to 12 months, but it can last longer. In the PMA approval process, the FDA must determine that a proposed device is safe and effective for its intended use based, in part, on extensive data, including but not limited to, technical, nonclinical, clinical trial, manufacturing and labeling data. The process for obtaining a PMA is more costly and uncertain and approval can take anywhere from at least one year to, in some cases, multiple years from the time the application is initially filed with the FDA. Modifications to products that are approved through a PMA application generally require further FDA approval. Some of our future products may require PMA approval. In addition, the FDA may demand that we obtain a PMA prior to marketing future changes of our existing products. Further, we may not be able to obtain additional 510(k) clearances or PMAs for new products or for modifications to, or additional indications for, our products in a timely fashion or at all. Delays in obtaining future clearances or approvals could adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn could harm our revenue and future profitability.

In order to conduct a clinical investigation involving human subjects for the purpose of demonstrating the safety and effectiveness of a medical device, if necessary, for a PMA application or 510(k) notification, a company must, among other things, apply for and obtain institutional review board ("IRB") approval of the proposed investigation. In addition, if the clinical study involves a "significant risk" (as defined by the FDA) to human health, the sponsor of the investigation must also submit and obtain FDA approval of an investigational device exemption ("IDE") application and follow applicable IDE regulations. Unless IDE-exempt, nonsignificant risk devices are still subject to certain abbreviated IDE requirements, but an IDE application is not required if such abbreviated requirements are met. We may not be able to obtain any necessary FDA and/or IRB approval to undertake clinical trials in the United States for future devices we develop and intend to market in the United States. If we do obtain such approvals, the FDA may find that our studies do not comply with the IDE or other regulations governing clinical investigations or the data from any such trials may not support clearance or approval of the investigational device. Moreover, certainty that clinical trials will meet desired endpoints, produce meaningful or useful data and be free of unexpected adverse effects, or that the FDA will accept the validity of foreign clinical study data (if applicable) cannot be assured, and such uncertainty could preclude or delay market clearance or authorizations resulting in significant financial costs and reduced revenue.

We are also subject to numerous post-marketing regulatory requirements, which include quality system regulations related to the manufacture of our devices, labeling regulations and medical device reporting ("MDR") regulations. The last of these regulations requires us to report to the FDA if our devices cause or contribute to a death or serious injury, or malfunction in a way that would likely cause or contribute to a death or serious injury if the malfunction recurred. If we fail to comply with present or future regulatory requirements that are applicable to us, we may be subject to enforcement action by the FDA, which may include any of the following sanctions:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- customer notification, or orders for repair, replacement or refunds;
- voluntary or mandatory recall or seizure of our current or future products;
- administrative detention by the FDA of medical devices believed to be adulterated or misbranded;
- operating restrictions, suspension or shutdown of production;
- refusal of our requests for 510(k) clearance or PMA of new products, new intended uses or modifications to existing products;
- rescission of 510(k) clearance or suspension or withdrawal of PMAs that have already been granted; and
- criminal prosecution.

The occurrence of any of these events may have a material adverse effect on our business, financial condition and results of operations.

Our employees, independent contractors, consultants, manufacturers and suppliers may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, consultants, manufacturers and suppliers may engage in fraudulent or illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates: (i) the laws of the FDA and other similar foreign regulatory bodies, including those laws requiring the reporting of true, complete and accurate information to such regulators; (ii) manufacturing standards; (iii) healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws; or (iv) laws that require the true, complete

and accurate reporting of financial information or data. These laws may impact, among other things, future sales, marketing and education programs. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commissions, certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials.

Although we have a code of business conduct and ethics, it is not always possible to identify and deter misconduct by our employees and other third parties, and the precautions we take to detect and prevent these activities may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of significant fines or other sanctions, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, disgorgement, individual imprisonment, additional integrity reporting and oversight obligations, possible exclusion from participation in Medicare, Medicaid and other government healthcare programs, contractual damages, reputational harm, diminished profits and future earnings and curtailment of operations, any of which could adversely affect our ability to operate our business and our results of operations. Whether or not we are successful in defending against any such actions or investigations, we could incur substantial costs, including legal fees, and divert the attention of management in defending ourselves against any of these claims or investigations, which could have a material adverse effect on our business, financial condition and results of operations.

There is no guarantee that the FDA will grant 510(k) clearance or premarket approval of our future products, and failure to obtain necessary clearances or approvals for our future products would adversely affect our ability to grow our business.

Some of our new or modified products will require FDA clearance of a 510(k) notification or FDA approval of a PMA application. The FDA may refuse our requests for 510(k) clearance or PMA of new products or may not clear or approve these products for the indications that are necessary or desirable for successful commercialization. Early stage review may also result in delays or other issues. For example, the FDA has issued guidance intended to explain the procedures and criteria used in assessing whether 510(k) and PMA submissions should be accepted for substantive review. Under the “Refuse to Accept” guidance, the FDA conducts an early review against specific acceptance criteria to inform 510(k) and PMA submitters if the submission is administratively complete, or if not, to identify the missing element(s). Submitters are given the opportunity to provide the FDA with any information identified as missing. If the information is not provided within a specified time, the submission will not be accepted for FDA review. The FDA may also change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions that may prevent or delay approval or clearance of our products under development or impact our ability to gain clearance or approval for modifications to our currently approved or cleared products in a timely manner. Significant delays in receiving clearance or approval, or the failure to receive clearance or approval for our new products would have an adverse effect on our ability to expand our business.

Recent initiatives by the FDA to enhance and modernize various regulatory pathways for device products and its overall approach to safety and innovation in the medical technology industry creates the possibility of changing product development costs, requirements, and other factors and additional uncertainty for our future products and business.

Regulatory requirements may change in the future in a way that adversely affects us. Any change in the laws or regulations that govern the clearance and approval processes or the post-market compliance requirements relating to our current and future products could make it more difficult and costly to obtain clearance or approval for new products, or to produce, market and distribute existing products.

For example, the FDA and other government agencies have been focusing on the cybersecurity risks associated with certain medical devices and encouraging device manufacturers to take a more proactive approach to assessing the cybersecurity risks of their devices both during development and on a periodic basis after the devices are in commercial distribution. These regulatory efforts could lead to new FDA requirements in the future or additional product liability or other litigation risks if any of our products is considered to be susceptible to third-party tampering. In December 2016, Congress passed the 21st Century Cures Act, which made multiple changes to the FDA’s rules for medical devices as well as for clinical trials, and in September 2022, Congress passed the Medical Device User Fee reauthorization package, which affects medical device regulation both pre- and post-approval and could have certain impacts on our business. In recent years, the FDA has also considered a series of efforts to modernize and streamline the 510(k) notification and regulatory review process and monitoring post-market safety. For example, in October 2022, FDA announced that 510(k) applications may be submitted electronically using the electronic submission template and resource, or eSTAR. Further, changes in the FDA 510(k) process could make clearance more difficult to obtain, increase delay, add uncertainty and have other significant adverse effects on our ability to obtain and maintain clearance for our products.

It is unclear at this time whether and how various activities initiated or announced by the FDA to modernize the U.S. medical device

regulatory system could affect our business, as some of the FDA's new medical device safety and innovation initiatives have not been formalized and remain subject to change. In response to the COVID-19 public health emergency, the FDA's device and diagnostic center leadership has exercised a significant amount of enforcement discretion to meet the medical community's and patients' needs for remote monitoring and other innovative solutions that involve digital health products. In December 2021, FDA issued draft guidance documents describing a phased transition process for medical devices that were developed or modified during the course of the pandemic to treat COVID-19 patients or allow greater access to patients, including medical imaging devices that were developed or modified in accordance with FDA's Enforcement Policy for Imaging Systems During the COVID-19 Public Health Emergency. It is unclear how these policies could impact the medical device industry in the future.

If we fail to obtain regulatory authorizations in other countries for existing products or products under development, we will not be able to commercialize these products in those countries.

In order for us to market our products in countries outside of the United States, we must comply with extensive safety and quality regulations in other countries regarding the quality, safety and efficacy of our products. These regulations, including the requirements for marketing authorizations, and the time required for regulatory review, vary from country to country. Failure to obtain regulatory authorization in any foreign country in which we plan to market our products may harm our ability to generate revenue and harm our business. Marketing authorization requirements vary between countries and can involve additional product testing and additional administrative review periods. The time required to obtain marketing authorization in other countries might differ from that required to obtain FDA clearance or other marketing authorization. The regulatory process in other countries may include all of the risks detailed above regarding FDA clearance in the United States. Regulatory authorization of a product in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory authorization in one country may negatively impact the regulatory process in others. Failure to obtain regulatory authorization in other countries or any delay or setback in obtaining such authorization could have the same adverse effects described above regarding FDA clearance in the United States.

The primary regulatory environment in Europe is that of the European Economic Area ("EEA"), which is comprised of the Member States of the European Union, Iceland, Liechtenstein and Norway. In 2023, our Swoop® system received CE marking, but we cannot be certain that we will be successful in meeting and continuing to meet the requirements to market a medical device in the EEA, particularly in light of the transition to the Medical Device Regulation. The Medical Device Regulation became fully effective on May 26, 2021. Compared to the MDD, the Medical Device Regulation promotes a shift from the pre-approval stage (i.e., the path to CE Marking) to a life-cycle approach and places greater emphasis on clinical data and clinical evaluations to assure the safety and performance of new medical devices. Moreover, the Medical Device Regulation includes elements intended to strengthen the conformity assessment procedures, assert greater control over notified bodies and their standards, increase overall system transparency, and impose more robust device vigilance requirements on manufacturers and distributors.

Among other changes, many device manufacturers will need to switch notified bodies to ones that received specific designation under the Medical Device Regulation, which will require those manufacturers to undergo an audit and have all their documentation reviewed by the new notified body before it can assess their medical device products under the new standards. The new rules and procedures that have been created under the overhauled EU regulations will likely result in increased regulatory oversight of all medical devices marketed in the EU, and this may, in turn, increase the costs, time and requirements that need to be met in order to place an innovative or high-risk medical device on the EEA market.

If we, our current or future contract manufacturers, or our current or future component suppliers are unable to manufacture our products in sufficient quantities, on a timely basis, at acceptable costs and in compliance with regulatory and quality requirements, the manufacturing and distribution of our devices could be interrupted, and our product sales and operating results could suffer.

When producing and distributing commercial medical device products, we, our contract manufacturer, and certain of our component suppliers are required to comply with the FDA's Quality System Regulation ("QSR"), which is a complex regulatory framework that covers the procedures and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage, shipping and servicing of our devices. Compliance with applicable regulatory requirements is subject to continual review and is monitored rigorously through periodic, sometimes unannounced, inspections by the FDA. We cannot assure investors that our facilities or our third-party manufacturers' or suppliers' facilities would pass any future quality system inspection. Failure of us or our third-party manufacturers and component suppliers to adhere to QSR requirements or take adequate and timely corrective action in response to an adverse quality system inspection finding could delay production of our products and lead to fines, difficulties in obtaining marketing authorizations for our products, recalls, or enforcement actions, including but not limited to injunctive relief or consent decrees, or other consequences, which could have a material adverse effect on our business, financial condition or results of operations. Any such failure, including the failure of our current or any future contract manufacturers to achieve and maintain the required high manufacturing standards, could result in further delays or failures in product testing or delivery, cost overruns, increased warranty costs or other problems that could harm our business and prospects.

In addition, any of our products shipped internationally are also required to comply with applicable quality standards and regulatory requirements, including the International Organization for Standardization ("ISO") quality system standards as well as European

Directives and norms in order to produce products for sale in the EU. In addition, many countries such as Canada and Japan have very specific additional regulatory requirements for quality assurance and manufacturing. If we fail to continue to comply with current good manufacturing requirements, as well as ISO or other regulatory standards, we may be required to cease all or part of our operations until we comply with these regulations. Maintaining compliance with multiple regulators adds complexity and cost to our manufacturing and compliance processes.

Our current or future products may be subject to product recalls even after receiving FDA clearance or approval. A recall of our products, either voluntarily or at the direction of the FDA, or the discovery of serious safety issues with our products, could have a significant adverse impact on us.

The FDA and similar governmental bodies in other countries have the authority to require the recall of our products if we or our third-party manufacturers fail to comply with relevant regulations pertaining to, among other things, manufacturing practices, labeling, advertising or promotional activities, or if new information is obtained concerning the safety or efficacy of these products. For example, under the FDA's Medical Device Reporting regulations, we are required to report to the FDA any incident in which our marketed products may have caused or contributed to a death or serious injury or in which our marketed products malfunctioned in a manner likely to cause or contribute to death or serious injury if that malfunction were to recur. Repeated adverse events or product malfunctions may result in a voluntary or involuntary product recall, or administrative or judicial seizure or injunction, when warranted. A government-mandated recall may be ordered if the FDA finds that there is a reasonable probability that the device would cause serious, adverse health consequences or death. A voluntary recall by us could occur as a result of any material deficiency in a device, such as manufacturing defects, labeling deficiencies, packaging defects or other failures to comply with applicable regulations. In general, if we decide to make a change to our marketed product, we are responsible for determining whether to classify the change as a recall. It is possible that the FDA could disagree with our initial classification. The FDA requires that certain classifications of recalls be reported to the FDA within 10 working days after the recall is initiated. If a change to a device addresses a violation of the federal Food, Drug, and Cosmetic Act ("FDCA"), that change would generally constitute a medical device recall and require submission of a recall report to the FDA.

Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our reputation, results of operations and financial condition, which could impair our ability to produce our products in a cost-effective and timely manner in order to meet our customers' demands. We may also be subject to product liability claims, be required to bear other costs, or be required to take other actions that may have a negative impact on our future sales and our ability to generate profits. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA. We may initiate voluntary recalls, field corrections, or removals involving our products in the future that we determine do not require notification to the FDA. If the FDA disagrees with our determinations, the FDA could require us to report those actions as recalls. A future recall, withdrawal, or seizure of any product could materially and adversely affect consumer confidence in our brands, lead to decreased demand for our products and negatively affect our sales. In addition, the FDA could take enforcement action for failing to report recalls when they were conducted by us or one of our agents.

We may be subject to enforcement action if we engage in improper or off-label marketing or promotion of our commercial medical device products, including fines, penalties and injunctions.

Our promotional materials and training methods must comply with FDA and other applicable laws and regulations, including the prohibition of the promotion of unapproved, or off-label, uses of lawfully marketed medical device products. Physicians may, however, use our commercial products off-label, as the FDA does not restrict or regulate a physician's practice of medicine. Medical device manufacturers and distributors are only permitted to promote their products in a way that is consistent with the FDA-authorized labeling and indications for use. If the FDA determines that our promotional materials or training materials promote a cleared or approved medical device in a manner inconsistent with our labeling, the agency could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance of an Untitled Letter or a Warning Letter or seeking injunction, seizure, civil fines or criminal penalties. In addition to ensuring that the claims we make are consistent with our regulatory clearances or approvals, the FDA also ensures that promotional labeling for all regulated medical devices is neither false nor misleading.

It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our promotional or training materials to constitute promotion of an off-label use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In that event, our reputation could be damaged, and adoption of our products could be impaired. Although our policy is to refrain from making statements or from disseminating promotional material that could be considered off-label promotion of our commercial medical device products, the FDA or another regulatory agency could disagree and conclude that we have engaged in off-label promotion. In addition, the off-label use of our products may increase the risk of product liability claims. Product liability claims are expensive to defend and could divert our management's attention, result in substantial damage awards against us, and harm our reputation. Recent court decisions have impacted the FDA's enforcement activity regarding off-label promotion in light of First Amendment considerations, although there are still significant risks in this area in part due to potential False Claims Act exposure. Further, this area is subject to ongoing policy changes at the federal level, resulting in

some degree of uncertainty for regulated businesses. For example, in August 2021 the FDA issued a final rule revising the agency's regulation governing the types of evidence relevant to determining the "intended use" of a drug or device under the FDCA, which has significant implications for when a manufacturer or distributor has engaged in off-label marketing.

Digital marketing and social media efforts may expose us to additional regulatory scrutiny, including from the Federal Trade Commission (the "FTC") and other consumer protection agencies and regulators.

In addition to the laws and regulations enforced by the FDA, advertising for various services and for non-restricted medical devices is subject to federal truth-in-advertising laws enforced by the FTC, as well as comparable state consumer protection laws. Our efforts to promote prescription medical device products via social media initiatives may subject us to additional scrutiny of our practices. For example, the FTC and other consumer protection agencies scrutinize all forms of advertising (whether in digital or traditional formats) for business services, consumer-directed products, and non-restricted medical devices to ensure that advertisers are not making false, misleading or unsubstantiated claims or failing to disclose material relationships between the advertiser and its products' endorsers, among other potential issues. The FDA oversees the advertising and promotional labeling for restricted medical devices and ensures, among other things, that there is effective communication of, and a fair and balanced presentation of, the risks and benefits of such high-risk medical devices.

Under the Federal Trade Commission Act ("FTC Act"), the FTC is empowered, among other things, to (a) prevent unfair methods of competition and unfair or deceptive acts or practices in or affecting commerce; (b) seek monetary redress and other relief for conduct injurious to consumers; and (c) gather and compile information and conduct investigations relating to the organization, business, practices, and management of entities engaged in commerce. The FTC has very broad enforcement authority, and failure to abide by the substantive requirements of the FTC Act and other consumer protection laws can result in administrative or judicial penalties, including injunctions affecting the manner in which we would be able to market services or products in the future, or criminal prosecution. We plan to increase our advertising activities that may be subject to these federal and state truth-in-advertising laws. Any actual or perceived non-compliance with those laws could lead to an investigation by the FTC or a comparable state agency or could lead to allegations of misleading advertising by private plaintiffs. Any such action against us could disrupt our business operations, cause damage to our reputation, and have a material adverse effect on our business.

Because we do not require extensive training for users of our current products, although they are limited under the FDA's marketing clearances to use by, and that images generated from the scanner be interpreted by, trained healthcare practitioners, there exists a potential for misuse of these products, misinterpretation of images by untrained professionals or misuse of these products by untrained professionals, which could ultimately harm our reputation and business.

Federal regulations allow us to sell our medical device products to or on the order of practitioners licensed by law to use or order the use of a prescription device. The definition of "licensed practitioners" varies from state to state. As a result, our current products may be purchased or operated by physicians with varying levels of training and, in many states, by non-physicians, including nurse practitioners, chiropractors and technicians. The FDA clearances of the products require interpretation of images by trained physicians and use of that information in determining a diagnosis. Outside the United States, many jurisdictions do not require specific qualifications or training for purchasers, or operators or interpreters, of medical device products. We do not supervise the procedures performed with our products, nor can we require that direct medical supervision occur. Although product training is offered, we do not require purchasers or operators of our non-invasive products to attend training sessions. The lack of required training and the purchase and use of our non-invasive products by non-physicians may result in product misuse and adverse treatment outcomes, which could harm our reputation and expose us to costly product liability litigation.

We are subject to federal, state and foreign laws prohibiting "kickbacks" and false or fraudulent claims, and other fraud and abuse laws, transparency laws, and other healthcare laws and regulations, which, if violated, could subject us to substantial penalties. Additionally, any challenge to or investigation into our practices under these laws could cause adverse publicity and be costly to respond to, and thus could harm our business.

Our relationships with customers and third-party payors are subject to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain our sales, marketing and other promotional activities by limiting the kinds of financial arrangements, including sales programs and certain customer and product support programs, we may have with hospitals, physicians or other purchasers of medical devices. Other federal and state laws generally prohibit individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent, or are for items or services that were not provided as claimed. These laws include, among others, the federal Anti-Kickback Statute, the federal civil False Claims Act, other federal healthcare false statement and fraud statutes, the Open Payments program, the Civil Monetary Penalties Law, and analogous fraud and abuse and transparency laws in most states, as described in "*Item 1. Business - Government Regulation*." Although the federal laws generally apply only to products or services for which payment may be made by a government healthcare program, state laws often apply regardless of whether federal funds may be involved.

While we believe and strive to ensure that our business arrangements with third parties and other activities and programs comply with all applicable laws, these laws are complex, and our activities may be found not to be compliant with one or more of these laws, which may result in significant civil, criminal and/or administrative penalties, fines, damages and exclusion from participation in government healthcare programs. Even an unsuccessful challenge or investigation into our practices could cause adverse publicity, and be costly to respond to, and thus could have a material adverse effect on our business, financial condition and results of operations. Our compliance with Medicare and Medicaid regulations may be reviewed by federal or state agencies, including the Office of Inspector General for the U.S. Department of Health and Human Services ("HHS-OIG"), Centers for Medicare & Medicaid Services ("CMS"), and the Department of Justice, or may be subject to whistleblower lawsuits under federal and state false claims laws. To ensure compliance with Medicare, Medicaid and other regulations, government agencies conduct periodic audits of the Company to ensure compliance with various supplier standards and billing requirements.

Similarly, our international operations are subject to the provisions of the FCPA, which prohibits U.S. companies and their intermediaries from making payments in violation of law to non-U.S. government officials for the purpose of obtaining or retaining business or securing any other improper advantage. In many countries, the healthcare professionals that medical device distributors regularly interact with may meet the definition of a foreign official for purposes of the FCPA. International business operations are also subject to various other international anti-bribery laws such as the U.K. Anti-Bribery Act. Despite meaningful measures that we undertake to facilitate lawful conduct, which include training and compliance programs and internal policies and procedures, we may not always prevent unauthorized, reckless or criminal acts by our employees or agents, or employees or agents of businesses or operations we may acquire. Violations of these laws, or allegations of such violations, could disrupt operations, involve significant management distraction and have a material adverse effect on our business, financial condition and results of operations, among other adverse consequences.

If we are found to have violated laws protecting the confidentiality of health information, we could be subject to civil or criminal penalties, which could increase our liabilities and harm our reputation or our business.

There are a number of federal and state laws protecting the confidentiality of certain health information and restricting the use and disclosure of that protected information. In particular, the U.S. Department of Health and Human Services promulgated privacy rules and security standards and breach notification rules under the Health and Insurance Portability and Accountability Act ("HIPAA"). These rules protect medical records and other identifiable health information by limiting their use and disclosure, giving individuals the right to access, amend and seek accounting of the uses and disclosures of their own health information and limiting most use and disclosures of health information to the minimum amount reasonably necessary to accomplish the intended purpose of the use or disclosure. When we provide services to our customers involving access to information protected under HIPAA, such as troubleshooting and maintenance of our products, we are functioning as a "business associate" under HIPAA, obligated to comply with much of HIPAA's privacy rule, all of HIPAA's security standards and also HIPAA breach notification requirements. As a business associate, we are subject to direct enforcement by the HHS Office for Civil Rights and state attorneys general, and we are also subject to audit and investigation. If we are found to be in violation of applicable HIPAA requirements, we could subject our customers or healthcare provider partners to civil or criminal penalties, which could increase our liabilities, harm our reputation and have a material adverse effect on our business, financial condition and results of operations.

We are subject to complex and evolving U.S. and foreign laws and regulations regarding privacy, data protection, and other matters. Many of these laws and regulations are subject to change and uncertain interpretation, and could result in claims, changes to our business practices, monetary penalties, increased cost of operations, or declines in customer growth or engagement, or otherwise harm our business.

We are subject to a variety of laws and regulations in the United States and abroad that involve matters central to our business, including laws and regulations relating to privacy, data sharing and data protection, artificial intelligence and use of machine learning, rights of publicity, content, intellectual property, advertising, marketing, distribution, data security, data retention and deletion, personal information, electronic contracts and other communications, competition, protection of minors, consumer protection, telecommunications, product liability, taxation, economic or other trade prohibitions or sanctions, corrupt practices, fraud, waste and abuse restrictions, and securities law compliance. The introduction of new products or expansion of our activities in certain jurisdictions may subject us to additional laws and regulations. For example, in addition to data protection laws passed by the federal government, many states and foreign countries have implemented their own data protection laws, some of which may apply simultaneously and conflict with federal law. Many of these laws create consumer rights including the right to know what personal information is collected, the right to know whether the data is sold or disclosed and to whom, the right to request that a company delete personal information collected, the right to opt-out of the sale of personal information and the right to non-discrimination in terms of price or service when a consumer exercises a privacy right. If we fail to comply with these regulations, we could be subject to civil sanctions, including fines and penalties for noncompliance.

In addition, foreign data protection, privacy, and other laws and regulations can be more restrictive than those in the United States. Data localization laws in some countries generally mandate that certain types of data collected in a particular country be stored and/or processed within that country. We could be subject to audits in Europe and around the world, particularly in the areas of consumer and

data protection, as we continue to grow and expand our operations. Legislators and regulators may make legal and regulatory changes, or interpret and apply existing laws, in ways that make our products less useful to customers, require us to incur substantial costs, expose us to unanticipated civil or criminal liability, or cause us to change our business practices. These changes or increased costs could negatively impact our business and results of operations in material ways. For example, the general data privacy regulation ("GDPR") imposes requirements in the EEA relating to, among other things, consent to process personal data of individuals, the information provided to individuals regarding the processing of their personal data, the security and confidentiality of personal data, notifications in the event of data breaches and use of third-party processors. GDPR also imposes restrictions on the transfer of personal data from the EEA to third countries like the United States. If we fail to comply with these standards, we could be subject to criminal penalties and civil sanctions, including fines and penalties and amounts could be significant.

Cybersecurity risks and cyber incidents could result in the compromise of confidential data or critical data systems and give rise to potential harm to customers, remediation and other expenses, expose us to liability under federal or state law, consumer protection laws, or other common law theories, subject us to litigation and federal and state governmental inquiries, damage our reputation, and otherwise be disruptive to our business and operations.

Cyber incidents can result from deliberate attacks or unintentional events. We collect and store on our networks sensitive information, including intellectual property, proprietary business information and personally identifiable information of individuals, such as our employees and customers. The secure maintenance of this information and technology is critical to our business operations. We have implemented multiple layers of security measures to protect the confidentiality, integrity and availability of these data and the systems and devices that store and transmit such data. We utilize current security technologies, including encryption and data depersonalization, and our defenses are monitored and routinely tested. Despite these efforts, threats from malicious persons and groups, new vulnerabilities and advanced new attacks against information systems create risk of cybersecurity incidents. These incidents can include, but are not limited to, gaining unauthorized access to digital systems for purposes of misappropriating assets or sensitive information, corrupting data, or causing operational disruption. Because the techniques used to obtain unauthorized access, disable or degrade service, or sabotage systems change frequently and may not immediately produce signs of intrusion, we may be unable to anticipate these incidents or techniques, timely discover them, or implement adequate preventative measures.

Cybersecurity threats can come from a variety of sources and may range in sophistication from an individual hacker to malfeasance by employees, consultants or other service providers to state-sponsored attacks. Cyber threats may be generic, or they may be custom-crafted against our information systems. Over the past several years, cyber-attacks have become more prevalent and much harder to detect and defend against. In addition, hardware, software or applications that we develop or procure from third parties may contain defects in design or manufacture or other problems that could unexpectedly compromise information security. Unauthorized parties may also attempt to gain access to our systems or facilities through fraud, trickery or other forms of deceiving employees, contractors and temporary staff.

There can be no assurance that we will not be subject to cybersecurity incidents that bypass our security measures, impact the integrity, availability or privacy of health information or other data subject to privacy laws or disrupt our information systems, devices or business, including our ability to deliver services to our users. As a result, cybersecurity, physical security and the continued development and enhancement of our controls, processes and practices designed to protect our enterprise, information systems and data from attack, damage or unauthorized access remain a priority for us. As cyber threats continue to evolve, we may be required to expend significant additional resources to continue to modify or enhance our protective measures or to investigate and remediate any cybersecurity vulnerabilities. The occurrence of any of these events could result in:

- harm to customers and end-users;
- business interruptions and delays;
- the loss, misappropriation, corruption or unauthorized access of data;
- state and/or federal government enforcement;
- significant fines and penalties;
- litigation, including potential class action litigation, and potential liability under privacy, security and consumer protection laws or other applicable laws;
- reputational damage;

- increase to insurance premiums; and
- foreign, federal and state governmental inquiries, any of which could have a material, adverse effect on our financial position and results of operations and harm our business reputation.

Security breaches, loss of data and other disruptions could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation.

In the ordinary course of our business, we collect and store sensitive data, and intellectual property and proprietary business information owned or controlled by us or our users. This data encompasses a wide variety of business-critical information, including research and development information, commercial information, and business and financial information. We face four primary risks relative to protecting this critical information: loss of access; inappropriate disclosure; inappropriate modification; and inadequate monitoring of our controls over the first three risks.

The secure processing, storage, maintenance, and transmission of this critical information is vital to our operations and business strategy, and we devote significant resources to protecting such information. Although we take measures to protect sensitive information from unauthorized access or disclosure, our information technology and infrastructure may be vulnerable to attacks by hackers or viruses, breaches, interruptions due to employee error, malfeasance, lapses in compliance with privacy and security mandates, or other disruptions. Any such breach or interruption could compromise our networks and the information stored there could be accessed by unauthorized parties, publicly disclosed, lost, or stolen.

Any such security breach or interruption, as well as any action by us or our employees or contractors that might be inconsistent with the rapidly evolving data privacy and security laws and regulations applicable within the United States and elsewhere where we conduct business, could result in enforcement actions by U.S. states, the U.S. federal government or foreign governments, liability or sanctions under data privacy laws that protect personally identifiable information, regulatory penalties, other legal proceedings such as but not limited to private litigation, the incurrence of significant remediation costs, disruptions to our development programs, business operations and collaborations, diversion of management efforts and damage to us and our brands' reputation, which could harm our business and operations. Because of the rapidly moving nature of technology and the increasing sophistication of cybersecurity threats, our measures to prevent, respond to and minimize such risks may be unsuccessful.

As a HIPAA business associate, we comply with HIPAA security standards. Whenever possible, we work with de-identified information and employ additional measures such as encryption tools to protect the privacy of our users and their patients' data. However, hackers may attempt to penetrate our computer systems, and, if successful, misappropriate personal or confidential business information. In addition, contractors or other third parties with whom we do business may attempt to circumvent our security measures or inadvertently cause a breach involving such information. While we continue to implement additional protective measures to reduce the risk of and detect cyber incidents, cyber-attacks are becoming more sophisticated and frequent, and the techniques used in such attacks change rapidly.

In addition, the GDPR, which took effect in May 2018, governs the collection and use of personal data of European Union residents. The GDPR, which is wide-ranging in scope, imposes requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals regarding the processing of their personal data, the security and confidentiality of the personal data, data breach notification and the use of third-party processors in connection with the processing of the personal data. The GDPR also imposes strict rules on the transfer of personal data out of the European Union to third countries like the United States, enhances enforcement authority and imposes large penalties for noncompliance, including the potential for fines of up to 20 million euros or 4% of the annual global revenues of the infringer, whichever is greater. While we comply with the GDPR, including reviewing our security procedures and entering into data processing agreements with relevant contractors, there can be no assurance that as our operations evolve, our efforts to comply or to remain in compliance will be fully successful.

Further, unauthorized access, loss or dissemination of sensitive personal data, such as health information, could also disrupt our operations, including our ability to conduct research and development activities, process and prepare company financial information, manage various general and administrative aspects of our business and damage our reputation, any of which could adversely affect our business and reputation. In addition, there can be no assurance that we will promptly detect any such disruption or security breach, if at all. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our products could be delayed.

Broad-based domestic and international government initiatives to reduce spending, particularly those related to healthcare costs, may reduce reimbursement rates for medical procedures, or make it more difficult for customers to purchase our products and services, all of which could adversely affect our business.

Healthcare reforms, changes in healthcare policies and changes to third-party coverage and reimbursements, including legislation enacted reforming the U.S. healthcare system and both domestic and foreign healthcare cost containment legislation, and any future changes to such legislation, may affect demand for our products and services and may have a material adverse effect on our financial condition and results of operations. The ongoing implementation of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, (the "ACA") in the United States, as well as state-level healthcare reform proposals, could reduce medical procedure volumes and impact the demand for medical device products or the prices at which we can sell products. The impact of healthcare reform legislation, and practices including price regulation, competitive pricing, comparative effectiveness of therapies, technology assessments, and managed care arrangements are uncertain. There can be no assurance that current levels of reimbursement will not be decreased in the future, or that future legislation, regulation, or reimbursement policies of third parties will not adversely affect the demand for our products and services or our ability to sell products and provide services on a profitable basis. The adoption of significant changes to the healthcare system in the United States, the EEA or other jurisdictions in which we may market our products and services, could limit the prices we are able to charge for our products and services or the amounts of reimbursement available for our products and services, could limit the acceptance and availability of our products and services, reduce medical procedure volumes and increase operational and other costs.

In addition, as a result of various judicial and Congressional challenges to certain aspects of the ACA, certain sections of the ACA have not been fully implemented or were effectively repealed. Following several years of litigation in the federal courts, in June 2021, the U.S. Supreme Court upheld the ACA when it dismissed a legal challenge to its constitutionality. Further legislative and regulatory changes under the ACA remain possible, but it is unknown what form any such changes or any law would take, and how or whether it may affect the medical device industry as a whole or our business in the future. In addition to the ACA, there have been and will likely continue to be other federal and state changes that affect the provision of healthcare goods and services in the United States. While we are unable to predict what changes may ultimately be enacted, to the extent that future changes affect how our products and services are paid for and reimbursed by government and private payers, our business could be adversely impacted. Moreover, complying with any new legislation or reversing changes implemented under the ACA could be time-intensive and expensive, resulting in a material adverse effect on the business.

Furthermore, many of our customers are healthcare facilities that are subject to state Determination of Need, or DoN, laws. The purpose of DoN laws is generally to promote competition and cost containment in healthcare. Under state DoN laws, healthcare facilities are required to complete an extensive review and approval process before making substantial capital expenditures. While our Swoop® system is generally more affordable than traditional MRI systems, in some states healthcare facilities are required to complete such processes in connection with their potential acquisition of a Swoop® system, which can result in delays in or decisions not to complete the sale process, resulting in an adverse impact on our business.

Risks Related to our Intellectual Property

If we are unable to obtain and maintain and enforce sufficient intellectual property protection for our products and technology, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our products may be impaired.

We rely on patent protection as well as trademark, copyright, trade secret and other intellectual property right protection and contractual restrictions to protect our proprietary products and technologies, all of which provide limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. If we fail to obtain, maintain and sufficiently enforce our intellectual property, third parties may be able to compete more effectively against us. In addition, we may incur substantial litigation costs in our attempts to recover damages or restrict use of our intellectual property.

To the extent our intellectual property offers inadequate protection, or is found to be invalid or unenforceable, we would be exposed to a greater risk of direct competition. If our intellectual property does not provide adequate coverage against our competitors' products, our competitive position could be adversely affected, as could our business, financial condition, results of operations and prospects. Both the patent application process and the process of managing patent and other intellectual property disputes can be time-consuming and expensive.

Our success depends in large part on our and our licensors' ability to obtain and maintain protection of the intellectual property we may own solely or jointly with, or license from, third parties, particularly patents, in the United States and other countries directed to our products and technologies. We apply for patents covering our products and technologies and uses thereof, as we deem appropriate. However, obtaining and enforcing patents is costly, time-consuming and complex, and we may fail to apply for patents on important products and technologies in a timely fashion or at all, or we may fail to apply for patents in potentially relevant jurisdictions. We may

not be able to file and prosecute all necessary or desirable patent applications, or maintain, enforce and license any patents that may issue from such patent applications, at a reasonable cost or in a timely manner or in all jurisdictions. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, we may not develop additional proprietary products, methods and technologies that are patentable. We may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the rights to patents licensed from or to third parties. Therefore, these patents and applications may not be prosecuted, obtained and enforced by such third parties in a manner consistent with the best interests of our business.

In addition, the patent position of life sciences and medical technology companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. Changes in either the patent laws or in interpretations of patent laws in the United States or other countries or regions may diminish the value of our intellectual property. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights presents some degree of uncertainty. It is possible that some of our pending patent applications will not result in issued patents in a timely fashion or at all, and even if patents are granted, they may not provide a basis for intellectual property protection of commercially viable products or services, may not provide any competitive advantages, or may be challenged, narrowed and/or invalidated by third parties. There exists some degree of uncertainty over the breadth of claims that may be allowed or enforced in our patents or in third-party patents. It is possible that third parties will attempt to design around our current or future patents such that we cannot prevent such third parties from using similar technologies and commercializing similar products to compete with us. Some of our owned or licensed patents or patent applications may be challenged at a future point in time and we may not be successful in defending any such challenges made against our patents or patent applications. Any successful third-party challenge to our patents could result in the narrowing, unenforceability or invalidity of such patents and increased competition to our business. The outcome of patent litigation or other proceedings can be uncertain, and any attempt by us to enforce our patent rights against others or to challenge the patent rights of others may not be successful, or, regardless of success, may take substantial time and result in substantial cost, and may divert our efforts and attention from other aspects of our business. Any of the foregoing events could have a material adverse effect on our business, financial condition and results of operations.

The U.S. law relating to the patentability of certain inventions in the life sciences and medical technology industry is uncertain and rapidly changing, which may adversely impact our existing patents or our ability to obtain patents in the future.

Changes in either the patent laws or interpretation of the patent laws in the United States or in other jurisdictions could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. For instance, under the Leahy-Smith America Invents Act (the “America Invents Act”), enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application is entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. These changes include allowing third-party submission of prior art to the United States Patent and Trademark Office (“USPTO”) during patent prosecution and additional procedures to challenge the validity of a patent through USPTO administered post-grant proceedings, including post-grant review, inter partes review, and derivation proceedings. The America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Various courts, including the U.S. Supreme Court, have rendered decisions that impact the scope of patentability of certain inventions or discoveries relating to life sciences and medical technology. Specifically, these decisions stand for the proposition that patent claims that recite laws of nature, natural phenomena, and abstract ideas are not themselves patentable unless those patent claims have sufficient additional features that provide practical assurance that the processes are genuine inventive applications of those laws, phenomena, and abstract ideas rather than patent drafting efforts designed to monopolize the law of nature, natural phenomenon, or abstract idea itself. What constitutes a “sufficient” additional feature is somewhat uncertain. Furthermore, in view of these decisions, since December 2014, the USPTO has published and continues to publish revised guidelines for patent examiners to apply when examining process claims for patent eligibility.

In addition, U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to some degree of uncertainty with regard to the Company’s ability to obtain patents in the future, this combination of events has created a degree of uncertainty with respect to the value of patents, once obtained. Depending on relevant laws enacted by the U.S. Congress, and decisions by the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that may have a material adverse effect on our ability to obtain new patents and to defend and enforce our existing patents and patents that we might obtain in the future.

Our patent portfolio may be negatively impacted by current uncertainties in the state of the law, new court rulings or changes in guidance or procedures issued by the USPTO or other similar patent offices around the world. From time to time, the U.S. Supreme Court, other federal courts, the U.S. Congress or the USPTO may change the standards of patentability, scope and validity of patents within the life sciences and medical technology and any such changes, or any similar adverse changes in the patent laws of other jurisdictions, could have a negative impact on our business, financial condition, prospects and results of operations.

We may not be able to protect our intellectual property rights throughout the world.

The laws of some foreign countries do not offer intellectual property rights to the same extent as the laws of the United States, and we and our licensors may encounter difficulties in obtaining, enforcing and defending such rights in foreign jurisdictions. Consequently, we and our licensors may not be able to prevent third parties from practicing our or our licensors' inventions in some or all countries outside the United States, or from selling or importing products made using our or our licensors' inventions in other jurisdictions. Competitors and other third parties may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and technologies and may also export infringing products to territories where we have patent protection, but enforcement practices or laws are not as strong as those in the United States. These products may compete with our products. Our and our licensors' patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. In addition, certain countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to other parties. Furthermore, many countries limit the enforceability of patents against other parties, including government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of any patents.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain other countries are not as developed or as favorable as the United States in the enforcement of patents and other intellectual property rights, which could make it difficult for us to stop the misappropriation or other violations of our intellectual property rights including infringement of our patents in such countries. The legal systems in certain countries may also favor state-sponsored companies or companies headquartered in particular jurisdictions over our first-in-time patents and other intellectual property rights. The absence of harmonized intellectual property protection laws and effective enforcement makes it difficult to ensure consistent respect for patent, trade secret, and other intellectual property rights on a worldwide basis. As a result, it is possible that we will not be able to enforce our rights against third parties that misappropriate our proprietary technology in those countries.

Proceedings to enforce our or our licensors' patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business, could put us and our licensors' patents at risk of being invalidated or interpreted narrowly and our and our licensors' patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We and our licensors may not prevail in any lawsuits that we or our licensors initiate, or that are initiated against us or our licensors, and the damages or other remedies awarded, if any, may not be commercially meaningful. In addition, changes in the law and legal decisions by courts in the United States and foreign countries may affect our ability to obtain adequate protection for our products, services and other technologies and the enforcement of intellectual property. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Any of the foregoing events could have a material adverse effect on our business, financial condition, results of operations and prospects.

Issued patents covering our products could be found invalid or unenforceable if challenged.

Our owned and licensed patents and patent applications may be subject to validity, enforceability and priority disputes. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability. Some of our patents or patent applications (including licensed patents and patent applications) may be challenged at a future point in time in opposition, derivation, reexamination, inter partes review, post-grant review or interference or other similar proceedings, as applicable. Any successful third-party challenge to our patents in this or any other proceeding could result in the unenforceability or invalidity of such patents, which may lead to increased competition to our business, which could have a material adverse effect on our business, financial condition, results of operations and prospects. In addition, if we or our licensors initiate legal proceedings against a third party to enforce a patent covering our products, the defendant could counterclaim that such patent covering our products, as applicable, is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. There are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent intentionally withheld relevant information from the relevant patent office, or knowingly made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include ex parte re-examination, inter partes review, post-grant review, derivation and equivalent proceedings in non-U.S. jurisdictions, such as opposition proceedings. Such proceedings could result in revocation of or amendment to our patents in such a way that they no longer cover and protect our products. With respect to the validity of our patents,

for example, we cannot be certain that there is no invalidating prior art of which we, our licensors, our patent counsel and the patent examiner were unaware during prosecution. The outcome following legal assertions of invalidity and unenforceability during patent litigation is unpredictable. If a defendant or other third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on certain aspects of our products and technologies, which could have a material adverse effect on our business, financial condition, results of operations and prospects. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license intellectual property, or develop or commercialize current or future products.

We may not be aware of all third-party intellectual property rights potentially relating to our products. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until approximately 18 months after filing or, in some cases, not until such patent applications issue as patents. We might not have been the first to make the inventions covered by each of our pending patent applications and we might not have been the first to file patent applications for these inventions. To determine the priority of these inventions, we may have to participate, as applicable, in interference proceedings, derivation proceedings or other post-grant proceedings declared by the USPTO, or other similar proceedings in non-U.S. jurisdictions that could result in substantial cost to us and the loss of valuable patent protection. The outcome of such proceedings is uncertain. No assurance can be given that other patent applications will not have priority over our patent applications. In addition, changes to the patent laws of the United States allow for various post-grant opposition proceedings that have not been extensively tested, and their outcome is therefore uncertain. Furthermore, if third parties bring these proceedings against our patents, regardless of the merit of such proceedings and regardless of whether we are successful, we could experience significant costs and our management may be distracted.

Any of the foregoing events could have a material adverse effect on our business, financial condition, results of operations and prospects.

If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be materially adversely affected and our business could be harmed.

We rely heavily on trade secrets and confidentiality agreements to protect our unpatented know-how, technology and other confidential proprietary information, and to maintain our competitive position. However, trade secrets and know-how can be difficult to protect. In particular, we anticipate that with respect to our technologies, these trade secrets and know-how will over time be disseminated within the industry through independent development, the publication of journal articles describing the methodology, and the movement of personnel from academic to industry scientific positions.

In addition to pursuing patents on our technology, we take steps to protect our intellectual property and proprietary technology by entering into agreements, including confidentiality agreements, non-disclosure agreements and intellectual property assignment agreements, with our employees, consultants, academic institutions, corporate partners and, when needed, our advisers. However, we cannot be certain that such agreements have been entered into with all relevant parties, and we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors or other third parties will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. For example, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Such agreements may not be enforceable or may not provide meaningful protection for our trade secrets or other proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements, and we may not be able to prevent such unauthorized disclosure, which could materially and adversely impact our ability to establish or maintain a competitive advantage in the market, and our business, financial condition, results of operations and prospects.

Monitoring unauthorized disclosure is difficult, and we do not know whether the steps we have taken to prevent such disclosure are, or will be, adequate. If we were to enforce a claim that a third party had wrongfully obtained and was using our trade secrets, it would be expensive and time-consuming, it could distract our personnel, and the outcome would be unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets or may not recognize certain claims of intellectual property infringement.

We also seek to preserve the integrity and confidentiality of our confidential proprietary information by maintaining physical security of our premises and physical and electronic security of our information technology systems, but it is possible that these security measures could be breached. If any of our confidential proprietary information were to be lawfully obtained or independently developed by a competitor or other third party, absent patent and copyright protection, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position. Competitors or third parties could purchase our products and attempt to replicate some or all of the competitive advantages we derive from our development efforts, design around our protected technology, develop their own competitive technologies that fall outside the scope of our intellectual property rights or independently develop our technologies without reference to our trade secrets. If any of our trade secrets were to be disclosed to or independently discovered by a competitor or other third party, it could materially and adversely affect our business, financial condition, results of operations and prospects.

We may be subject to claims challenging the inventorship and ownership of our patents and other intellectual property.

We or our licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in-licensed patents, trade secrets or other intellectual property as an inventor or co-inventor. For example, we or our licensors may have inventorship disputes arise from alleged inventors such as employees, consultants, advisors or others who are involved in developing our products, some of whom may have conflicting intellectual property ownership obligations. In addition, counterparties to our consulting, sponsored research, software development and other agreements may assert that they have an ownership interest in intellectual property developed under such arrangements. In particular, certain software development agreements pursuant to which certain third parties have developed parts of our proprietary software may not include provisions that expressly assign to us ownership of all intellectual property developed for us by such third parties. Furthermore, certain of our sponsored research agreements pursuant to which we provide certain research services for third parties do not assign to us all intellectual property developed under such agreements. As such, we may not have the right to use all such developed intellectual property under such agreements, we may be required to obtain licenses from third parties and such licenses may not be available on commercially reasonable terms or at all, or may be non-exclusive. If we are unable to obtain such licenses and such licenses are necessary for the development, manufacture and commercialization of our products and technologies, we may need to cease the development, manufacture or commercialization of our products and technologies. Litigation may be necessary to defend against these and other claims challenging inventorship of our or our licensors' ownership of our owned or in-licensed patents, trade secrets or other intellectual property. If we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. In such an event, we may be required to obtain licenses from third parties and such licenses may not be available on commercially reasonable terms or at all, or may be non-exclusive. If we are unable to obtain and maintain such licenses, we may need to cease the development, manufacture or commercialization of our products and technologies. Even if we are successful in defending against such claims, litigation could result in substantial costs and loss of time and be a distraction to management and other employees, and certain customers or partners may defer engaging with us until the particular dispute is resolved. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may not be able to protect and enforce our trademarks and trade names or build name recognition in our markets of interest thereby harming our competitive position.

The registered or unregistered trademarks or trade names that we own may be challenged, infringed, circumvented, declared generic or otherwise fail to function as a mark, lapsed or determined to be confusingly similar to or dilutive of other marks. We may not be able to protect our rights in these trademarks and trade names, which we need in order to build name recognition. In addition, third parties have filed, and may in the future file, for registration of trademarks similar or identical to our trademarks, thereby impeding our ability to build brand identity and possibly leading to consumer confusion. If such third parties were to succeed in registering or developing common law rights in any other trademarks that are similar or identical to our trademarks, and if we are not successful in challenging such rights and defending against challenges to Company's trademarks, we may not be able to use such trademarks to develop brand recognition of our technologies, products or services. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Further, we have and may in the future enter into agreements with owners of such third-party trade names or trademarks to avoid potential trademark litigation which may limit our ability to use our trade names or trademarks in certain fields of business. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business, financial condition, results of operations and prospects may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources. Any of the foregoing events could have a material adverse effect on our business, financial condition and results of operations.

Patent terms may be inadequate to protect our competitive position on our products for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a utility patent is generally 20 years from its earliest U.S. non-provisional filing date. While extensions may be available, the life of a patent, and the protection it affords, is limited. In the United States, a patent's term may, in certain cases, be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the USPTO in examining and granting a patent, or may be shortened if a patent is terminally disclaimed over a commonly owned patent or a patent naming a common inventor and having an earlier expiration date. Even if patents covering our products are obtained, once the patent life has expired, we may be open to competition from competitive products. If one of our products requires extended development, testing and/or regulatory review, patents protecting such products might expire before or shortly after such products are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to our products, which could have a material adverse effect on our business, financial condition and results of operations.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed to us alleged trade secrets of their other clients or former employers, which could subject us to costly litigation.

As is common in the life sciences and medical industry, we engage the services of consultants and independent contractors to assist us in the development of our products. Many of these consultants and independent contractors were previously employed at or may have previously or may be currently providing consulting or other services to, universities or other technology, medical device, biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may become subject to claims that we, a consultant or an independent contractor inadvertently or otherwise used or disclosed trade secrets or other information proprietary to their former employers or their former or current clients. We may similarly be subject to claims stemming from similar actions of an employee, such as one who was previously employed by another company, including a competitor or potential competitor. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team. If we are not successful, we could lose access or exclusive access to valuable intellectual property.

We may become involved in lawsuits to defend against third-party claims of infringement, misappropriation or other violations of intellectual property rights or to protect or enforce our intellectual property, any of which could be expensive, time consuming and unsuccessful, and may prevent or delay our development and commercialization efforts.

Our commercial success depends in part on our ability and the ability of future collaborators to develop, manufacture, market and sell our product and use our products and technologies without infringing, misappropriating or otherwise violating the intellectual property rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the life sciences and medical technology sector, as well as administrative proceedings for challenging patents, including interference, derivation, inter partes review, post grant review, and reexamination proceedings before the USPTO, or oppositions and other comparable proceedings in foreign jurisdictions. We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that our products, manufacturing methods, software and/or technologies infringe, misappropriate or otherwise violate their intellectual property rights. Numerous issued patents and pending patent applications that are owned by third parties exist in the fields in which we are developing our products and technologies. It is not always clear to industry participants, including us, the claim scope that may issue from pending patent applications owned by third parties or which patents cover various types of products, technologies or their methods of use or manufacture. Thus, because of the large number of patents issued and patent applications filed in our fields, there may be a risk that third parties, including our competitors, may allege they have patent rights encompassing our products, technologies or methods and that we are employing technology protected by such patent rights without authorization.

If third parties, including our competitors, believe that our products or technologies infringe, misappropriate or otherwise violate their intellectual property rights, such third parties may seek to enforce against us their intellectual property rights, including patent rights, by filing against us an intellectual property-related lawsuit, including a patent infringement lawsuit. Even if we believe third-party intellectual property claims are without merit, there is no assurance that a court would find in our favor on questions of infringement, validity, enforceability, or priority. If any third parties were to assert these or any other patents against us and we are unable to successfully defend against any such assertions, we may be required, including by court order, to cease the development and commercialization of the infringing products or technology and we may be required to redesign such products and technologies so they do not infringe such patents, which may not be possible or may require substantial monetary expenditures and time. We could also be required to pay damages, which could be significant, including treble damages and attorneys' fees if we are found to have willfully infringed such patents. We could also be required to obtain a license to such patents in order to continue the development and commercialization of the infringing product or technology. However, such a license may not be available on commercially reasonable terms or at all, including because certain of these patents may be held by or exclusively licensed to our competitors. Even if such a license were available, it may require substantial payments or cross-licenses under our intellectual property rights, and it may only be available on a nonexclusive basis, in which case third parties, including our competitors, could use the same licensed intellectual property to compete with us. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operation and prospects.

We may choose to challenge, including in connection with any allegation of patent infringement by a third party, the patentability, validity, ownership or enforceability of any third-party patent that we believe may have applicability in our field, and any other third-party patent that may at some future time possibly be asserted against us. Such challenges may be brought either in court or by requesting that the USPTO, European Patent Office ("EPO"), or other foreign patent offices review the patent claims, such as in an ex-parte reexamination, inter partes review, post-grant review proceeding or opposition proceeding or other similar proceedings. However, there can be no assurance that any such challenge by us or any third party will be successful. Even if such proceedings are successful, these proceedings are expensive and may consume our time or other resources, distract our management and technical personnel, and the costs of these opposition proceedings could be substantial. There can be no assurance that our defenses of non-infringement, invalidity or unenforceability will succeed.

Third parties, including our competitors, could be infringing, misappropriating or otherwise violating our solely owned and/or in-licensed intellectual property rights. Monitoring unauthorized use of intellectual property is difficult and costly. We may not be able to detect unauthorized use of, or take appropriate steps to enforce, our intellectual property rights. From time to time, we seek to analyze our competitors' products and services, and may in the future seek to enforce our rights based on potential infringement, misappropriation or violation of our intellectual property. However, the steps we take to protect our intellectual property rights may not be adequate to enforce our rights against such infringement, misappropriation or violation of our intellectual property. Any inability to meaningfully enforce our intellectual property rights could harm our ability to compete and reduce demand for our products and technologies.

Litigation proceedings may be necessary for us to enforce our patent and other intellectual property rights. In any such proceeding, a court may refuse to stop the other party from using the technology at issue on the grounds that our owned and in-licensed patents do not cover the technology in question. Further, in such a proceeding, the defendant could counterclaim that our intellectual property is invalid or unenforceable and the court may agree, in which case we could lose valuable intellectual property rights, which could allow third parties to commercialize technology or products similar to ours and compete directly with us, without payment to us. Alternatively or additionally, such a proceeding could result in requiring us to license rights from the prevailing party in order to be able to manufacture or commercialize our products without infringing such party's intellectual property rights, and if we are unable to obtain such a license, we may be required to cease commercialization of our products and technologies, any of which could have a material adverse effect on our business, financial condition, results of operations and prospects. The outcome in any such proceeding is somewhat unpredictable.

Regardless of whether we are defending against or asserting an intellectual property-related claim in an intellectual property-related proceeding that may be necessary in the future, and regardless of outcome, substantial costs and diversion of resources may result which could have a material adverse effect on our business, financial condition, results of operations and prospects. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions, or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our Class A common stock. Some of our competitors and other third parties may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. We may not have sufficient financial or other resources to adequately conduct these types of litigation or proceedings. Any of the foregoing, or any uncertainties resulting from the initiation and continuation of any litigation, could have a material adverse effect on our business, financial condition, results of operations and prospects. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar adverse effect on our business, financial condition, results of operations and prospects.

Obtaining and maintaining our patent protection depends on compliance with various required procedures, document submissions, fee payments and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States at several stages over the lifetime of the patents and/or applications. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In certain circumstances, we rely on our licensors to pay these fees due to the U.S. and non-U.S. patent agencies and to take the necessary action to comply with these requirements with respect to our licensed intellectual property. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which non-compliance can result in an irrevocable abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors may be able to enter the market without infringing our patents and this circumstance could have a material adverse effect on our business, financial condition, results of operations and prospects.

We currently rely on licenses from third parties, and in the future may rely on additional licenses from other third parties, and if we lose any of these licenses, then we may be subjected to future litigation.

We are, and may in the future become, a party to license agreements that grant us rights to use certain intellectual property, including patents and patent applications, typically in certain specified fields of use. We may need to obtain additional licenses from others to advance our research, development and commercialization activities.

Our success may depend in part on the ability of our licensors and any future licensors to obtain, maintain and enforce patent protection for our licensed intellectual property. Without protection for the intellectual property we license, other companies might be able to offer substantially identical products and technologies for sale, which could materially adversely affect our competitive business position and harm our business, financial condition, results of operations and prospects.

Our current license agreements impose, and future agreements may impose, various diligence, commercialization, milestone payment, royalty, insurance and other obligations on us and require us to meet development timelines, or to exercise commercially reasonable efforts to develop and commercialize licensed products, in order to maintain the licenses. If we fail to comply with these obligations, our licensor(s) may have the right to terminate our license, in which event we would not be able to develop or market products or technology covered by the licensed intellectual property. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

Moreover, disputes may also arise between us and our licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- our financial or other obligations under the license agreement;
- whether, and the extent to which, our products, technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensor(s); and
- the priority of invention of patented technology.

If we do not prevail in such disputes, we may lose any or all of our rights under such license agreements, experience significant delays in the development and commercialization of our products and technologies, or incur liability for damages, any of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. In addition, we may seek to obtain additional licenses from our licensor(s) and, in connection with obtaining such licenses, we may agree to amend our existing licenses in a manner that may be more favorable to the licensor(s), including by agreeing to terms that could enable third parties, including our competitors, to receive licenses to a portion of the intellectual property that is subject to our existing licenses and to compete with our products.

In addition, the agreements under which we currently and in the future license intellectual property or technology from third parties are complex and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize any affected products or services, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Absent the license agreements, we may infringe patents subject to those agreements, and if the license agreements are terminated, we may be subject to litigation by the licensor. Litigation could result in substantial costs and distract our management. If we do not prevail, we may be required to pay damages, including treble damages, attorneys' fees or costs and expenses and royalties, which could adversely affect our ability to offer products or services, our ability to continue operations and our business, financial condition, results of operations and prospects.

If we cannot license rights to use technologies on reasonable terms, we may not be able to commercialize new products in the future.

We may identify third-party technology that we may need to license or acquire in order to develop or commercialize our products or technologies. However, we may be unable to secure such licenses or acquisitions. The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us.

We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. In return for the use of a third party's technology, we may agree to pay the licensor royalties based on sales of our products or services. Royalties are a component of cost of products or technologies and affect the margins on our products. We may also need to negotiate licenses to patents or patent applications before or after introducing a commercial product. We may not be able to obtain necessary licenses to patents or patent applications, and our business may suffer if we are unable to enter into the necessary licenses on acceptable terms or at all, if any necessary licenses are subsequently terminated, if the licensor fails to abide by the terms of the license or fails to prevent infringement by third parties, or if the licensed intellectual property rights are found to be invalid or unenforceable.

Certain of our in-licensed patents are, and our future owned and in-licensed patents may be, subject to a reservation of rights by one or more third parties, including government march-in rights, that may limit our ability to exclude third parties from commercializing products similar or identical to ours.

In addition, our owned and in-licensed patents may be subject to a reservation of rights by one or more third parties. When new technologies are developed with government funding, in order to secure ownership of such patent rights, the recipient of such funding is required to comply with certain government regulations, including timely disclosing the inventions claimed in such patent rights to the U.S. government and timely electing title to such inventions. Any failure to timely elect title to such inventions may permit the U.S. government to, at any time, take title to such inventions. Additionally, the U.S. government generally obtains certain rights in any resulting patents, including a non-exclusive royalty-free license authorizing the government to use the invention or to have others use the invention on its behalf. If the government decides to exercise these rights, it is not required to engage us as its contractor in connection with doing so. In addition, these rights may permit the U.S. government to disclose our confidential information to third parties and to exercise march-in rights to use or allow third parties to use our licensed technology free of charge. The U.S. government can exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to U.S. industry. In addition, our rights in such inventions may be subject to certain requirements to manufacture products embodying such inventions in the United States. Any exercise by the government of any of the foregoing rights could have a material adverse effect on our business, financial condition, results of operations and prospects.

Our products contain third-party open source software components and failure to comply with the terms of the underlying open source software licenses could restrict our ability to sell our products and provide third parties access to our proprietary software.

Our products may contain software licensed by third parties under open source software licenses. Use and distribution of open source software may entail greater risks than use of third-party commercial software, as open source software licensors generally do not provide warranties or other contractual protections regarding infringement claims or the quality of the code. Some open source software licenses contain requirements that the licensee make its source code publicly available if the licensee creates modifications or derivative works using the open source software, depending on the type of open source software the licensee uses and how the licensee uses it. If we combine our proprietary software with open source software in a certain manner, we could, under certain open source software licenses, be required to release the source code of our proprietary software to the public for free. This would allow our competitors and other third parties to create similar products with less development effort and time and ultimately could result in a loss of our product sales and revenue, which could have a material adverse effect on our business, financial condition, results of operations and prospects. In addition, some companies that use third-party open source software have faced claims challenging their use of such open source software and their compliance with the terms of the applicable open source license. We may be subject to suits by third parties claiming ownership of what we believe to be open source software, or claiming non-compliance with the applicable open source licensing terms. Use of open source software may also present additional security risks because the public availability of such software may make it easier for hackers and other third parties to compromise or attempt to compromise our technology and systems.

Although we review our use of open source software to avoid subjecting our proprietary software to conditions we do not intend, the terms of many open source software licenses have not been interpreted by U.S. courts, and there is a risk that these licenses could be construed in a way that could impose unanticipated conditions or restrictions on our ability to commercialize our products and proprietary software. Moreover, our processes for monitoring and controlling our use of open source software in our products may not be effective. If we are held to have breached the terms of an open source software license, we could be subject to damages or be required to seek licenses from third parties to continue offering our products on terms that are not economically feasible, to re-engineer our products, to discontinue the sale of our products if re-engineering could not be accomplished on a timely basis, or to make generally available, in source code form, our proprietary code, any of which could adversely affect our business, financial condition, results of operations and prospects.

Intellectual property rights do not necessarily address all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make products that are similar to products and technologies we may develop or utilize similar technology that are not covered by the claims of the patents that we own or license now or in the future;
- we, or our licensor(s), might not have been the first to make the inventions covered by the issued patent or pending patent application that we license or may own in the future;
- we, or our licensor(s), might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing, misappropriating or otherwise violating our owned or licensed intellectual property rights;
- it is possible that our pending licensed patent applications or those that we may own in the future will not lead to issued patents;
- issued patents that we own, in-license, or otherwise hold rights to may be held invalid or unenforceable or have their scope narrowed, including as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; and
- we may choose not to file a patent application for certain trade secrets or know-how, and a third party may subsequently file a patent application covering such intellectual property.

Should any of these events occur, they could materially adversely affect our business, financial condition, results of operations and prospects.

Litigation Risks

We face the risk of product liability claims and may be subject to damages, fines, penalties and injunctions, among other things.

Our business exposes us to the risk of product liability claims that are inherent in the testing, manufacturing and marketing of medical devices, including those which may arise from the misuse (including system hacking or other unauthorized access by third parties to our systems) or malfunction of, or design flaws in, our hardware and software products. This liability may vary based on the FDA classification associated with our devices and with the state law governing product liability standards applied to specification developers and/or manufacturers in a given negligence or strict liability lawsuit. We may be subject to product liability claims if our products cause, or merely appear to have caused, an injury. Claims may be made by patients, healthcare providers or others selling our products. The risk of product liability claims may also increase if our products are subject to a product recall or seizure. Product liability claims may be brought by individuals or by groups seeking to represent a class.

Although we have insurance at levels that we believe to be appropriate, this insurance is subject to deductibles and coverage limitations. Our current product liability insurance may not continue to be available to us on acceptable terms, if at all, and, if available, the coverage may not be adequate to protect us against any future product liability claims. Further, if additional medical device products are approved or cleared for marketing, or if we launch additional 510(k)-exempt device products or products that are not FDA-regulated medical devices, we may seek additional insurance coverage. If we are unable to obtain insurance at an acceptable cost or on acceptable terms with adequate coverage or otherwise protect against potential product liability claims, we will be exposed to significant liabilities, which may harm our business. A product liability claim, recall or other claim with respect to uninsured liabilities or for amounts in excess of insured liabilities could result in significant costs and significant harm to our business.

We may be subject to claims against us even if the apparent injury is due to the actions of others or misuse of the device or a partner device. Healthcare providers may use our products in a manner inconsistent with the products' labeling and that differs from the manner in which they were used in clinical studies and authorized by the FDA. Off-label use of products by healthcare providers is common, and any such off-label use of our products could subject us to additional liability, or require design changes to limit this potential off-label use once discovered. Defending a suit, regardless of merit, could be costly, could divert management attention and might result in adverse publicity, which could result in the withdrawal of, or result in reduced acceptance of, our products in the market.

Additionally, we have entered into various agreements where we indemnify third parties for certain claims relating to our products. These indemnification obligations may require us to pay significant sums of money for claims that are covered by these indemnification obligations. We are not currently subject to any product liability claims; however, any future product liability claims against us, regardless of their merit, may result in negative publicity about us that could ultimately harm our reputation and could have a material adverse effect on our business, financial condition, results of operations and prospects.

Risks Related to Our Securities and to Being a Public Company

We identified material weaknesses in our internal control over financial reporting. If our remediation measures are ineffective, or if we experience additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls in the future, we may not be able to report our financial condition or results of operations accurately or in a timely manner and we may be unable to maintain compliance with applicable stock exchange listing requirements, which may adversely affect investor confidence in us and, as a result, materially and adversely affect our business and the value of our Class A common stock.

In connection with Legacy Hyperfine's and Liminal's combined financial statement close process for the years ended December 31, 2020 and 2019, we identified a material weakness in our internal control over financial reporting. We outsourced our accounting and financial reporting to 4Catalyzer Corporation ("4Catalyzer") and as of and during the years ended December 31, 2020 and 2019, did not have our own finance function to appropriately perform the supervision and review of the information received from 4Catalyzer and assess its reasonableness and accuracy.

In addition, HealthCor previously recorded a portion of its Class A ordinary shares subject to possible redemption in permanent equity. Notwithstanding the presence of maximum redemption thresholds or charter provisions common in SPACs that provide a limitation on redemptions that would cause a SPAC's net tangible assets to be less than $5,000,001, in accordance with SEC Staff guidance on redeemable equity instruments, ASC 480-10-S99, "*Distinguishing Liabilities from Equity*", and EITF Topic D-98, "*Classification and Measurement of Redeemable Securities*", and, according to the SEC Staff communications with certain independent auditors, redemption provisions not solely within the control of the issuing company require ordinary shares subject to redemption to be classified outside of permanent equity. Although HealthCor did not specify a maximum redemption threshold in its Articles and Restated Memorandum and Articles of Association (the "HealthCor Articles"), the HealthCor Articles provided that HealthCor could not redeem its public shares in an amount that would cause its net tangible assets to be less than $5,000,001. In light of the recent SEC Staff communications with certain independent auditors, HealthCor's management re-evaluated the effectiveness of its disclosure controls and procedures as of September 30, 2021. Based upon that evaluation, HealthCor concluded that the misclassification of the Class A ordinary shares was quantitatively material to individual line items within the balance sheet. This resulted in a restatement of the initial carrying value of the Class A ordinary shares subject to possible redemption, with the offset recorded to additional paid-in capital (to the extent available), accumulated deficit and ordinary shares.

The foregoing represents material weaknesses in our internal controls over financial reporting. A "material weakness" is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented, or detected and corrected on a timely basis.

In light of the material weaknesses identified and the resulting restatement, we plan to enhance our processes to identify and appropriately apply applicable accounting requirements to better evaluate and understand the nuances of the complex accounting standards that apply to our financial statements. Our management is in the process of implementing a remediation plan, which includes, without limitation, the hiring of additional accounting and finance personnel with technical public company accounting and financial reporting experience. The material weaknesses will not be considered remediated until management designs and implements effective controls that operate for a sufficient period of time and management has concluded through testing that these controls are effective.

The elements of our remediation plan can only be accomplished over time, and we can offer no assurance that these initiatives will ultimately have the intended effects or that other material weaknesses and control deficiencies will not be discovered in the future.

If our efforts are not successful or other material weaknesses or control deficiencies occur in the future, we may be unable to report our financial results accurately on a timely basis or help prevent fraud, which could cause our reported financial results to be materially misstated and result in the loss of investor confidence or delisting and cause the market price of our shares to decline. We cannot assure you that the initiatives we have taken to date, or any initiatives we may take in the future, will be sufficient to avoid potential future material weaknesses.

We could fail to maintain the listing of our Class A common stock on Nasdaq, which could seriously harm the liquidity of our shares and our ability to raise capital or complete a strategic transaction.

The Nasdaq Stock Market has established continued listing requirements, including a requirement to maintain a minimum closing bid price of at least $1.00 per share. In December 2022, we received written notice from Nasdaq notifying us that, because the closing bid price for our Class A common stock has fallen below $1.00 per share for 30 consecutive business days, we no longer meet the minimum bid price requirement for continued inclusion on The Nasdaq Global Market. In February 2023, we received a letter from Nasdaq indicating that we had regained compliance with the bid price requirement. However, there can be no assurance that we will be able to maintain compliance with the bid price requirement or other Nasdaq requirements in the future. If we are not able to maintain compliance with Nasdaq requirements, our Class A common stock may be delisted from Nasdaq, which could have a material adverse effect on us and our stockholders, including by reducing the liquidity of our shares and having a material adverse effect on our ability to raise capital or complete a strategic transaction.

Because we are a "controlled company" within the meaning of the Nasdaq listing rules, our stockholders may not have certain corporate governance protections that are available to stockholders of companies that are not controlled companies.

So long as more than 50% of the voting power for the election of our directors is held by an individual, a group or another company, we will qualify as a "controlled company" under the Nasdaq listing rules. As of February 15, 2023, Dr. Rothberg controls approximately 85% of the voting power of our outstanding capital stock. As a result, we are a "controlled company" under the Nasdaq rules and are not subject to the requirements that would otherwise require us to have: (i) a majority of our board of directors consist of independent directors; (ii) director nominees selected, or recommended for our board of directors' selection, either by a majority of the independent directors or a nominating committee comprised solely of independent directors; and (iii) a compensation committee comprised solely of independent directors.

Dr. Rothberg may have his interest in the Company diluted due to future equity issuances or his own actions in selling shares of our Class B common stock, in each case, which could result in a loss of the "controlled company" exemption under the Nasdaq listing rules. We would then be required to comply with those provisions of the Nasdaq listing rules.

The dual class structure of our common stock has the effect of concentrating voting power with Jonathan M. Rothberg, Ph.D., Vice Chairperson of our board of directors and the Founder of Legacy Hyperfine and Liminal, which will limit an investor's ability to influence the outcome of important transactions, including a change in control.

Shares of our Class B common stock have 20 votes per share, while shares of our Class A common stock have one vote per share. Dr. Rothberg and his permitted transferees hold all of the issued and outstanding shares of our Class B common stock, and as of February 15, 2023, Dr. Rothberg holds approximately 85% of the voting power of our capital stock and is able to control matters submitted to our stockholders for approval, including the election of directors, amendments of our organizational documents and any merger, consolidation, sale of all or substantially all of our assets or other major corporate transactions. Dr. Rothberg may have interests that differ from yours and may vote in a way with which you disagree and which may be adverse to your interests. This concentrated control may have the effect of delaying, preventing or deterring a change in control of the Company, could deprive our stockholders of an opportunity to receive a premium for their capital stock as part of a sale of the Company, and might ultimately affect the market price of shares of our Class A common stock. If additional shares of our Class B common stock are issued, your shares and your votes may be significantly diluted.

Potential conflicts of interest may arise among the holders of our Class B common stock and the holders of our Class A common stock.

Dr. Rothberg and his permitted transferees hold all of our Class B common stock. As a result, conflicts of interest may arise among Dr. Rothberg, on the one hand, and the Company and holders of our Class A common stock on the other hand. Dr. Rothberg has the ability to influence our business and affairs through his ownership of the high vote shares of our common stock, his general ability to elect our board of directors, and provisions in the Charter requiring his approval for certain corporate actions (in addition to approval by our board of directors). If the holders of our Class A common stock are dissatisfied with the performance of our board of directors, they have no ability to remove any of our directors, with or without cause.

Further, through his ability to elect our board of directors and as well as his service on our board of directors, Dr. Rothberg has the ability to influence the determination of the amount and timing of our investments and dispositions, cash expenditures, indebtedness, issuances of shares of common stock, tax liabilities and amounts of reserves.

Delaware law and provisions in our Charter and bylaws could make a takeover proposal more difficult.

Our organizational documents are governed by Delaware law. Certain provisions of Delaware law and of our Charter and bylaws could discourage, delay, defer or prevent a merger, tender offer, proxy contest or other change of control transaction that a stockholder might consider in its best interest, including those attempts that might result in a premium over the market price for the shares of our Class A common stock held by our stockholders. These provisions provide for, among other things:

- the ability of our board of directors to issue one or more series of preferred stock;
- stockholder action by written consent only until the first time when Dr. Rothberg and his permitted transferees cease to beneficially own shares of Class B common stock representing 50% or more of the voting power of the outstanding shares of our capital stock;
- certain limitations on convening special stockholder meetings;
- advance notice for nominations of directors by stockholders and for stockholders to include matters to be considered at our annual meetings;
- amendment of certain provisions of the organizational documents only by the affirmative vote of holders of (i) a majority of the voting power of the shares of our capital stock so long as Dr. Rothberg and his permitted transferees beneficially own shares of Class B common stock representing 50% or more of the voting power of the outstanding shares of our capital stock and (ii) at least two-thirds of the voting power of the shares of capital stock from and after the time that Dr. Rothberg and his permitted transferees cease to beneficially own shares of Class B common stock representing 50% or more of the voting power of our voting stock; and
- a dual-class common stock structure with 20 votes per share of our Class B common stock, the result of which is that Dr. Rothberg has the ability to control the outcome of matters requiring stockholder approval, even though Dr. Rothberg owns less than a majority of the outstanding shares of our capital stock.

These anti-takeover provisions as well as certain provisions of Delaware law could make it more difficult for a third party to acquire the Company, even if the third party's offer may be considered beneficial by many of our stockholders. As a result, our stockholders may be limited in their ability to obtain a premium for their shares. If prospective takeovers are not consummated for any reason, we may experience negative reactions from the financial markets, including negative impacts on the price of our Class A common stock. These provisions could also discourage proxy contests and make it more difficult for our stockholders to elect directors of their choosing and to cause us to take other corporate actions that our stockholders desire.

Our Charter designates the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings and the federal district courts as the sole and exclusive forum for other types of actions and proceedings, in each case, that may be initiated by our stockholders, which could limit our stockholders' ability to obtain what such stockholders believe to be a favorable judicial forum for disputes with the Company or our directors, officers or other employees.

Our Charter provides that, unless we consent to the selection of an alternative forum, any (i) derivative action or proceeding brought on behalf of us; (ii) action asserting a claim of breach of a fiduciary duty owed by, or any other wrongdoing by, any current or former director, officer, other employee or stockholder of us; (iii) action asserting a claim against us arising pursuant to any provision of the Delaware General Corporation Law ("DGCL") or our Charter or our bylaws or as to which the DGCL confers jurisdiction on the Court of Chancery; (iv) action to interpret, apply, enforce, or determine the validity of any provisions in the certificate of incorporation of bylaws; or (v) action asserting a claim governed by the internal affairs doctrine, shall, to the fullest extent permitted by law, be exclusively brought in the Court of Chancery of the State of Delaware or, if such court does not have subject matter jurisdiction thereof, the federal district court of the State of Delaware. Subject to the foregoing, the federal district courts of the United States are the exclusive forum for the resolution of any action, suit or proceeding asserting a cause of action under the Securities Act. The exclusive forum provision does not apply to suits brought to enforce any liability or duty created by the Exchange Act. Any person or entity purchasing or otherwise acquiring or holding an interest in any shares of our capital stock shall be deemed to have notice of and to have consented to the forum provisions in our Charter. These choice-of-forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that he, she or it believes to be favorable for disputes with the Company or our directors, officers or other employees or stockholders, which may discourage such lawsuits. We note that there is uncertainty as to whether a court would enforce these provisions and that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. Section 22 of the Securities Act creates concurrent jurisdiction for state and federal courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder.

Alternatively, if a court were to find these provisions of our Charter inapplicable or unenforceable with respect to one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could materially adversely affect our business, financial condition and results of operations and result in a diversion of the time and resources of our management and board of directors.

Changes in laws or regulations, or a failure to comply with any laws and regulations, or any litigation that we may be subject to or involved in may adversely affect our business, investments and results of operations.

We are subject to laws, regulations and rules enacted by national, regional and local governments and the Nasdaq Stock Market on which our securities are listed. In particular, we are required to comply with certain SEC, Nasdaq, Delaware and other legal and regulatory requirements. Compliance with, and monitoring of, applicable laws, regulations and rules may be difficult, time-consuming and costly.

Those laws, regulations and rules and their interpretation and application may also change from time to time and those changes could have a material adverse effect on our business, investments and results of operations. For example, it is difficult to predict what impact, if any, changes in federal laws and policies, including those relating to tax, environmental, labor and employment, will have on our business and industry, the economy as a whole, consumer confidence and discretionary spending. Further, a recent ruling by the Court of Chancery in Delaware introduced uncertainty as to whether Section 242(b)(2) of the Delaware General Corporation Law ("DGCL") required a separate vote in favor of at least a majority of the outstanding shares of Class A common stock, in addition to a vote in favor of at least a majority of the outstanding shares of Class A and Class B common stock, voting together as a single class, to properly authorize shares of Class A common stock. In connection with the Business Combination, our stockholders authorized an increase in the number of shares of Class A common stock under Cayman Islands law, our jurisdiction at the time of the stockholder vote. Accordingly, we do not believe that the Delaware ruling applies to us. However, any failure to comply with applicable laws, regulations or rules, as interpreted and applied, could have a material adverse effect on our business and results of operations. Claims alleging that a portion of our Class A common stock was not authorized could lead to shares of our Class A common stock being voidable and have a material adverse effect on us and our prospects. In addition, uncertainty with respect to our capitalization resulting from the Court of Chancery's ruling referenced above could have a material adverse impact on us, including on our ability to complete equity financing transactions or issue stock-based compensation to our employees, directors and officers until the underlying issues are definitively resolved. This uncertainty could impair our ability to execute our business plan, attract and retain employees, management and directors and adversely affect our commercial relationships.

We are an emerging growth company and a smaller reporting company within the meaning of the Securities Act, and we may take or continue to take advantage of certain exemptions from disclosure requirements available to emerging growth companies or smaller reporting companies, which could make our securities less attractive to investors and may make it more difficult to compare our performance with other public companies.

We are an "emerging growth company" within the meaning of the Securities Act, as modified by the JOBS Act, and we may take or continue to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. As a result, our stockholders may not have access to certain information they may deem important. We could be an emerging growth company for up to five years, although circumstances could cause us to lose that status earlier, including if the market value of our Class A common stock held by non-affiliates is $700 million or more as of the last business day of the most recently completed second fiscal quarter, in which case we would no longer be an emerging growth company as of the end of that fiscal year. We cannot predict whether investors will find our securities less attractive because we will rely on these exemptions. If some investors find our securities less attractive as a result of our reliance on these exemptions, the trading prices of our securities may be lower than they otherwise would be, there may be a less active trading market for our securities and the trading prices of our securities may be more volatile.

Further, Section 102(b)(1) of the JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies (that is, those that have not had a Securities Act registration statement declared effective or do not have a class of securities registered under the Exchange Act) are required to comply with the new or revised financial accounting standards. The JOBS Act provides that a company can elect to opt out of the extended transition period and comply with the requirements that apply to non-emerging growth companies but any such election to opt out is irrevocable. We have elected not to opt out of such extended transition period which means that when a standard is issued or revised and it has different application dates for public or private companies, we, as an emerging growth company, can adopt the new or revised standard at the time private companies adopt the new or revised standard. This may make comparison of our financial statements with another public company which is not an emerging growth company or is an emerging growth company which has opted out of using the extended transition period difficult or impossible because of the potential differences in accountant standards used.

Additionally, we are a "smaller reporting company" as defined in Item 10(f)(1) of Regulation S-K. Smaller reporting companies may take advantage of certain reduced disclosure obligations, including, among other things, providing only two years of audited financial statements. We are required to reflect a determination that we are no longer a smaller reporting company in our quarterly report on Form 10-Q for the first fiscal quarter of the next fiscal year after the fiscal year in which (i) the market value of our common stock held by non-affiliates is greater than or equal to $250 million as of the end of that fiscal year's second fiscal quarter, and (ii) if our annual revenues are not greater than or equal to $100 million during the last completed fiscal year, the market value of our common stock held by non-affiliates is $700 million or more as of the end of that fiscal year's second fiscal quarter. To the extent we take advantage of such reduced disclosure obligations, it may also make comparison of our financial statements with other public companies difficult or impossible.

Reports published by analysts, including projections in those reports that differ from our actual results, could adversely affect the price and trading volume of our Class A common stock.

Securities research analysts may establish and publish their own periodic projections for us. Those projections may vary widely and may not accurately predict the results we actually achieve. Our share price may decline if our actual results do not match the projections of these securities research analysts. Similarly, if one or more of the analysts who write reports on us downgrades our stock or publishes inaccurate or unfavorable research about our business, our share price could decline. In addition, securities research analysts may compare us to companies that are not appropriately comparable, which could lead to lower than expected valuations. If one or more analysts cease coverage of us or fail to publish reports on us regularly, our share price or trading volume could decline.

Our business and operations could be negatively affected if we become subject to any securities litigation or shareholder activism, which could cause us to incur significant expense, hinder execution of our business and growth strategy and impact our stock price.

In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been brought against that company. Shareholder activism, which could take many forms or arise in a variety of situations, has been increasing recently. Volatility in the stock price of our Class A common stock or other reasons may in the future cause us to become the target of securities litigation or shareholder activism. Securities litigation and shareholder activism, including potential proxy contests, could result in substantial costs and divert management's and the board of directors' attention and resources from our business. Additionally, such securities litigation and shareholder activism could give rise to perceived uncertainties as to our future, adversely affect our relationships with service providers and make it more difficult to attract and retain qualified personnel. Also, we may be required to incur significant legal fees and other expenses related to any securities litigation and activist shareholder matters. Further, our stock price could be subject to significant fluctuation or otherwise be adversely affected by the events, risks and uncertainties of any securities litigation and shareholder activism.

The grant of registration rights pursuant to the Registration Rights Agreement, the PIPE Subscription Agreements and the Letter Agreement, and the future exercise of such rights, may adversely affect the market price of our Class A common stock.

At the Closing, we, the Sponsor, certain affiliates of the Sponsor and certain stockholders of Legacy Hyperfine and Liminal entered into the Registration Rights Agreement, pursuant to which, among other things, the parties to the Registration Rights Agreement were granted certain registration rights (including demand and piggy-back rights, subject to cooperation and cut-back provisions) with respect to their respective shares of our common stock, in each case, on the terms and subject to the conditions therein. In particular, the Registration Rights Agreement requires that we use our commercially reasonable efforts to file a registration statement under the Securities Act to permit the public resale of all registrable securities as permitted by Rule 415 of the Securities Act and to cause such registration statement to be declared effective. The registration statement was initially filed on January 24, 2022 and declared effective by the SEC on February 1, 2022. The post-effective amendment to the registration statement filed on January 24, 2023 was declared effective by the SEC on January 30, 2023.

Further, pursuant to the Subscription Agreements and the Letter Agreement, we agreed (i) to file a registration statement with the SEC for the resale of the PIPE Securities by the PIPE Investors and the Letter Agreement Shares by Jefferies LLC and to use commercially reasonable efforts to cause such registration statement to be declared effective and (ii) to maintain the effectiveness of such registration statement until the earlier of (a) five years from the date of effectiveness of the initial registration statement, (b) the date on which PIPE Investors cease to hold the securities covered thereby, and (c) the date all of the securities covered thereby can be sold publicly without restriction or limitation under Rule 144 under the Securities Act. We will bear the cost of registering these securities. The registration statement was initially filed on January 24, 2022 and declared effective by the SEC on February 1, 2022. The post-effective amendment to the registration statement filed on January 24, 2023 was declared effective by the SEC on January 30, 2023. The registration and availability of such a significant number of securities for trading in the public market may have an adverse effect on the market price of our Class A common stock.

The obligations associated with being a public company will involve significant expenses and will require significant resources and management attention, which may divert from our business operations.

As a public company, we are subject to the reporting requirements of the Exchange Act and the Sarbanes-Oxley Act. The Exchange Act requires the filing of annual, quarterly and current reports with respect to a public company's business and financial condition. The Sarbanes-Oxley Act requires, among other things, that a public company establish and maintain effective internal control over financial reporting. As a result, we are incurring, and will continue to incur significant legal, accounting and other expenses that Legacy Hyperfine and Liminal did not previously incur. Our management team and many of our other employees will need to devote substantial time to compliance and may not effectively or efficiently manage our transition as a public company.

We do not intend to pay cash dividends for the foreseeable future.

We currently intend to retain our future earnings, if any, to finance the further development and expansion of our business and do not intend to pay cash dividends in the foreseeable future. Any future determination to pay dividends will be at the discretion of our board of directors and will depend on our financial condition, results of operations, capital requirements, and future agreements and financing instruments, business prospects and such other factors as our board of directors deems relevant.

Item 1B. UNRESOLVED STAFF COMMENTS

None.

Item 2. PROPERTIES

We currently maintain our principal executive offices at 351 New Whitfield Street, Guilford, Connecticut 06437. We also occupy office and laboratory space in Palo Alto, California. We lease office space under operating leases. We consider our current office space adequate for our current operations.

Item 3. LEGAL PROCEEDINGS

We are not currently a party to any material legal proceedings.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our Class A common stock is traded on The Nasdaq Global Market under the symbol "HYPR".

Stockholders

As of March 1, 2023, we had 55,991,074 outstanding shares of Class A common stock held by approximately 144 holders of record, 15,055,288 outstanding shares of Class B common stock held by approximately six holders of record, and no outstanding shares of preferred stock.

Unregistered Sales of Securities

Not applicable.

Issuer Purchases of Equity Securities

Not applicable.

Item 6. [RESERVED]

Not applicable.

Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS OF HYPERFINE

The following discussion and analysis of the financial condition and results of operations Hyperfine, Inc. and its subsidiaries (for purposes of this section, collectively referred as the "Company", "we," "us" and "our") should be read together with the audited combined and consolidated financial statements as of and for the years ended December 31, 2022 and 2021, together with the related notes thereto, included elsewhere in this Annual Report on Form 10-K. This discussion contains forward-looking statements and involves numerous risks and uncertainties, including, but not limited to, those described under the heading "Risk Factors." Actual results may differ materially from those contained in any forward-looking statements.

Overview

We are an innovative digital health business with a mission to provide affordable and accessible imaging and monitoring through magnetic resonance imaging ("MRI") to revolutionize healthcare for people around the world. Our Swoop® Portable Magnetic Resonance ("MR") Imaging® System™ ("Swoop® system") produces high-quality images at a lower magnetic field strength than conventional MRI scanners. Healthcare professionals can use the Swoop® system to make effective clinical diagnoses on a patient in various settings where MRI devices have previously been inaccessible. The easy-to-use interface and portable design of our Swoop® system make it accessible f anywhere in a hospital, clinic, or patient care site. We are working to realize our vision of providing affordable and accessible imaging of health conditions worldwide.

MRI is a medical imaging technique used in radiology to image the human body's anatomy and physiological processes. MRI is typically used in various clinical settings for medical diagnosis, the staging of disease, and follow-up treatment. Unlike X-ray computed tomography ("CT") or positron emission tomography ("PET"), MRI does not expose patients to harmful ionizing radiation. We believe MRI offers unrivaled clarity in assessing brain disorders and injuries.

Despite its advantages, many healthcare institutions worldwide lack the facilities, qualified operators, and capital necessary to acquire and maintain expensive MRI devices. The Swoop® system is intended for use at the patient's bedside in any professional healthcare facility, such as a physician's office or a critical care facility. The demand for MRI has been augmented by the aging population and the rising prevalence of cancer and cardiovascular, neurological, and orthopedic conditions. Healthcare professionals and insurers recognize imaging as a cost-effective and non-invasive diagnostic tool for evaluation and ongoing monitoring. The Swoop® system is the next generation MRI device designed to drive costs down and expand the current $28 billion imaging market.

We believe the adoption of the Swoop® system by healthcare professionals has benefits across healthcare communities in both high and low resource settings. Our technology allows us to provide decision support and rapid feedback for diagnostic insight for clinicians of various levels of expertise. Through our collaborations with the healthcare community, we have begun to optimize Hyperfine's software ecosystem to harness artificial intelligence ("AI") and cloud technology to transform the system into a bedside clinical decision support platform. These efforts seek to improve image quality, help users analyze images, and reduce the time to diagnosis. In December 2022, we suspended the development of our brain sensing platform, which was in the early stages of development to non-invasively measure key vital signs in the brain.

Legacy Hyperfine received initial 510(k) clearance from the U.S. Food and Drug Administration ("FDA") in 2020. The Swoop® system has since been authorized for brain imaging in several countries, including the European Union (CE marking), the United Kingdom (UKCA), Canada, Australia, New Zealand and Pakistan. The Swoop® system is 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. We are building our direct commercial infrastructure in the United States and plan to sell our products in other countries through direct sales or distributors
.

In December 2022, we committed to an organizational restructuring designed to decrease our costs and create a more streamlined organization to support our business. As a result, we terminated approximately 13% of our global workforce including, among others, the employees of our subsidiary, Liminal. In connection with the restructuring, we estimate we will incur up to $1.7 million of costs, of which we have incurred approximately $1.1 million as of December 31, 2022, consisting primarily of cash severance costs, other severance benefits, fixed asset impairment costs and other related restructuring costs. We expect to substantially complete the restructuring in the first quarter of 2023. The estimates of costs and expenses that we expect to incur in connection with the restructuring are subject to a number of assumptions and actual results may differ materially. We may also incur additional costs not currently contemplated due to events that may occur as a result of, or that are associated with, the restructuring.

COVID-19

In March 2020, the World Health Organization declared the global outbreak of COVID-19 to be a pandemic. We continue to closely monitor the recent COVID-19 developments, including the lifting of COVID-19 safety measures, the drop in COVID-19 vaccination rates, the implementation of, and reaction to, vaccine mandates, the spread of new strains or variants of the coronavirus, and supply chain and labor shortages. The COVID-19 pandemic has had, and is expected to continue to have, an adverse impact on our operations.

COVID-19 created multiple commercial challenges in 2022 and 2021 and the commercial challenges and restrictions from COVID-19 have been generally reduced in 2023. We experienced restrictions on our salesforce's ability to visit sites during 2022. During the second half of 2022, hospitals and other healthcare providers started to ease restrictions and our salesforce's ability to visit sites improved. Commercially, many hospitals and other healthcare providers decreased spending and limited physical access to facilities, slowing our ability to demonstrate our Swoop® system. In addition, many hospitals and other healthcare providers continue to focus their attention on addressing COVID-19, which we believe has resulted in lower sales volume. Trade shows and conferences moved to a virtual platform creating difficulty in demonstrating our device to key stakeholders. It was not uncommon to host virtual product demonstrations with 6-10 physicians, something that would ordinarily not happen or would take many weeks of planning to produce. While physician society conferences are beginning to ramp, attendance has remained below pre-pandemic levels. As such we continue to supplement the conferences with "Demo at Your Door" — demonstrations providing target customers hands-on device experience at a place of their choosing. Virtual demonstrations, even though they generated a lot of interest in our product, often did not result in sales, and all sales required an in-person product demonstration. As more conferences begin to be held in-person, we expect to improve our ability to provide product demonstrations to potential customers. It is unclear whether or not conferences will have the same in-person attendance as they would have had in the past.

Because the manufacturing of our Swoop® system was developed, and our commercial launch of our Swoop® system occurred, during the COVID-19 pandemic market and manufacturing conditions, we did not have to materially adjust our existing resource allocation or our factors of production because of the COVID-19 pandemic. However, if there are further waves of the COVID-19 pandemic, we may experience a greater negative impact in our supply chain than we have previously.

During the COVID-19 pandemic and the variants that followed, our suppliers agreed to shift new work to domestic suppliers to help reduce the risk of manufacturing delays. Our supplier and sub tier suppliers have been adversely affected by COVID-19. Although we work closely with our suppliers to attempt to ensure continuity of supply, the supply of certain components and raw materials used in our product has been and may continue to be slowed as a direct result of COVID-19 and its variants. We have also experienced increases in product costs as raw materials have been constrained. Prices have risen sharply over the past year, and lead times have extended dramatically, particularly on semiconductor products. Over the next 12 months, we expect prices to increase due to the raw material demand surges across numerous industries, along with labor and transportation related constraints. We also expect lead times to reduce as component production levels recover to meet demand. We helped to minimize the impact of the COVID-19 pandemic on the manufacturing of our product and operations by using our manufacturer's preferred suppliers, increasing communications with suppliers and freight carriers, and providing advanced forecasts and purchase orders for new and existing devices.

In addition, future regulatory authorizations by the FDA or other regulatory authorities may take longer because of COVID-19 pandemic-related delays, though we have not been impacted by such delays to date.

Please refer to the section titled, "Item 1A. Risk Factors" included elsewhere in this Annual Report on Form 10-K for more information. We are unable to predict the full impact that the COVID-19 pandemic will have on our future results of operations, liquidity and financial condition due to numerous uncertainties, including the duration of the pandemic and actions that may be taken by government authorities across the United States and elsewhere. We will continue to monitor the performance of our business and reassess the impacts of COVID-19.

Key Performance Metrics

We review the key performance measures discussed below to evaluate the business and measure performance, identify trends, formulate plans and make strategic decisions.

Installed Base

The Swoop® system total installed base consists of three components, discussed in further detail below: Commercial system installations (which make up total revenue), grant fulfillment installations, and research unit installations. The Swoop® system total installed base (or total installed units) is the number of Swoop® systems 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. As of December 31, 2022, the Company had a total of 107 Swoop® systems installed, including 25 research units which are installed, at no cost to the institutions, to expand clinical use cases.

Presented below is a breakout of total Swoop® systems installed as of December 31, 2022 and 2021:

	TOTAL INSTALLED UNITS	
	As of December 31, 2022	**As of December 31, 2021**
Commercial systems installations	62	27
Grant fulfillment installations	20	18
	82	45
Research units	25	25
Total Installed Units	107	70

Commercial system installations reflect device sales and subscription services through commercial agreements (commercial sales) or through research transfer agreements ("RTA") sales. Commercial sales are made to hospitals and other healthcare providers as direct sales of devices and software subscription and support services, or through subscriptions for the use of the device and software. RTA sales represent the sale of Swoop® systems or subscriptions for research use purposes. Our revenue for the years ended December 31, 2022 and 2021 is derived from commercial sales and RTA sales.

Grant fulfillment installations consist of shipments of Swoop® systems to hospitals and other clinical facilities designated by the Bill & Melinda Gates Foundation (“BMGF”). The corresponding funding for these installations from BMGF is recorded as a reduction in the research and development expenses when realized during the period.

Research units represent installed units, at no cost to the institutions, to expand clinical use cases. The installation of research units is recorded as a fixed asset with the related depreciation recorded as research and development expense over the life of the research unit.

Factors Affecting Results of Operations

The following factors have been important to our business and we expect them to impact our results of operations and financial condition in future periods:

Development and commercialization efforts on the Swoop® system

In addition to our efforts to develop and commercialize the Swoop® system, we were previously working to develop a non-invasive brain sensing technology that is more affordable, accessible, and safer, to enable healthcare professionals to more easily monitor key brain vital signs such as cerebral blood flow and intracranial pressure throughout patient care. In December 2022, we suspended our program to develop a device to non-invasively measure key vital signs in the brain to focus our resources on the continued development and commercialization of the Swoop® system.

Technical innovation

We have developed our device through extensive research and development activities. Our Swoop® system is designed to make the customer experience as easy as possible through our integrated, easy-to-use interface that portrays images on a tablet, smartphone or other WiFi capable device. In addition to this design, our team is focused on customer success programs that help integrate the Swoop® system into any hospital or clinic workflow. We believe that as the Swoop® system becomes integrated into intensive care units (ICUs) and sites across medical practices, we will gain more insights into our product’s usability and potentially develop automated analysis of images that we believe will lead to further efficiencies in patient diagnosis. We plan to continue developing our technology to expand into new imaging applications to enable us to reach the broader care continuum through diagnosis and treatment. In the future, we plan to introduce a further enhanced MRI system designed to conduct neuroimaging and imaging of other extremities for interventional procedures. In addition to our efforts to disrupt the MRI market, we see a significant opportunity to help patients in the neuromonitoring space. Although we expect these activities in technical innovation of the current device and new devices will increase our research and development expenses, we expect them to positively impact our results of operations and profitability in the future.

Expand sales in international markets

Revenue from non-U.S. countries was 37% of total revenue for the year ended December 31, 2022. We intend to continue to increase our sales and distribution capabilities outside of the United States to take advantage of the large international opportunity for our products. The countries in which we have begun commercializing our Swoop® system include the United Kingdom, Canada, Australia, New Zealand and Pakistan. We obtained a Medical Device License issued by Health Canada, UKCA certification in the United Kingdom, CE marking in the EU and regulatory authorization in Australia, New Zealand and Pakistan.

While we will maintain our commercial focus in the U.S. in 2023, our commitment to the vision of providing affordable and accessible imaging that enables earlier detection and remote management of health conditions worldwide is in part made possible by grant funding from the BMGF. Through our engagement with nonprofit organizations, we deployed the Swoop® system to low-middle resource settings without readily-accessible MRI technology. The multiple grants provided by the BMGF, which commenced funding in the spring of 2020, support the deployment of 45 Swoop® systems to investigators. At December 31, 2022, 20 Swoop® system units and 10 baby cradles were provisioned and delivered to BMGF and the majority of the milestones for service deliverables were also met. The ongoing investigation is designed to provide data to validate the potential use of the Swoop® system in measuring the impact of maternal anemia, malnutrition, infection, and birth-related injury.

Description of Certain Components of Financial Data

Sales

We derive our sales from the following sources: device sales and service sales as described in more detail below. Our revenue recognition policies are discussed in more detail under "*Summary of Significant Accounting Policies*" in Note 2 to our combined and consolidated financial statements and notes thereto for the years ended December 31, 2022 and 2021 included elsewhere in this Annual Report on Form 10-K.

Device: Device sales primarily consist of sales of our MRI devices.

Service: Service sales primarily consists of sales from subscriptions of bundled devices, maintenance, and software.

During the first quarter of 2022 and the first quarter of 2023, we have taken pricing actions by increasing the price of the device while lowering the price of the monthly subscription. This has resulted in higher device revenue per unit and lower service revenue per unit for sales under the subscription plus ownership model.

Cost of sales

Cost of sales consists of product and service costs including personnel cost and benefits including stock-based compensation, product costs, production setup expenses, depreciation and amortization expenses, inventory excess and obsolescence expenses.

Research and development

Research and development costs consist of production costs for prototype, test and pre-production units, lab supplies, consulting and personnel costs, including salaries, stock-based compensation, bonuses and benefit costs. Most of our research and development expenses are related to developing new products and services as well as to enhance our current product and software capabilities. Consulting expenses are related to research and development activities as well as clinical and regulatory activities. Fabrication services include certain third-party engineering costs. Research and development expenses are expensed as incurred. We expect to continue to make substantial investments in product development.

General and administrative

General and administrative expenses primarily consist of personnel costs and benefits including stock-based compensation, patent and filing fees, office expenses, technology expenses and outside services. Outside services consist of professional services, legal and other professional fees. Other related costs include additional facilities expenses and general corporate overhead to support the employee base.

Sales and marketing

Sales and marketing costs primarily consist of personnel costs and benefits including stock-based compensation, advertising, promotional costs, as well as costs for conferences, meetings, and other events. We will seek to control sales and marketing expenses while continuing to promote our brand through marketing and advertising initiatives and expand our market presence and awareness.

Interest income

Interest income primarily consists of interest earned on our cash equivalents invested in money market securities.

Other expense, net

Other expense, net primarily relates to foreign exchange gain or loss.

Provision for income taxes

We utilize the asset and liability method of accounting for income taxes, as set forth in Accounting Standards Codification ("ASC") 740, Income Taxes. Under this method, deferred tax assets and liabilities are recognized for the expected future tax consequences of temporary differences between the carrying amounts and the tax basis of assets and liabilities using the enacted statutory tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. A valuation allowance is established against net deferred tax assets if, based on the weight of available evidence, it is more-likely-than-not that some or all of the net deferred tax assets will not be realized. We recorded a full valuation allowance as of December 31, 2022 and 2021. Based on available evidence, we believe that it is more-likely-than-not that we will be unable to utilize all of our deferred tax assets in the future.

On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act") was enacted which included provisions related to net operating loss ("NOL") carryovers and carrybacks. The CARES Act amended the NOL carryback rules by allowing NOLs arising in tax years beginning after December 31, 2017 and before January 1, 2021 to be carried back to each of the 5 years preceding the year of the loss to generate a refund of previously paid income taxes. In addition, the CARES Act temporarily removed the 80% limitation under which NOLs generated post-2017 could be used to offset no more than 80% of taxable income, and allows for full use of such NOLs for tax years before January 1, 2021. We have evaluated the relevant provisions of the CARES Act and have determined that we do not expect to recognize any benefit related to these provisions due to our net operating losses in the current year and all prior years. Therefore, there are no income tax effects to be recognized in the combined and consolidated financial statements for the years ended December 31, 2022 and 2021.

Results of Operations

The following is a discussion of our results of operations for the periods shown below, and our accounting policies are described under *"Summary of Significant Accounting Policies"* in Note 2 in our combined and consolidated financial statements for the years ended December 31, 2022 and 2021 included elsewhere in this Annual Report on Form 10-K.

Comparison of the Years Ended December 31, 2022 and 2021 ($ Amounts in thousands)

	Year Ended December 31,		Change
($ Amounts in thousands)	**2022**	**2021**	**%**
Sales			
Device	$ 5,246	$ 715	633.7 %
Service	1,568	781	100.8 %
Total sales	$ 6,814	$ 1,496	355.5 %
Cost of Sales			
Device	$ 4,231	$ 2,058	105.6 %
Service	1,676	605	177.0 %
Total cost of sales	$ 5,907	$ 2,663	121.8 %
Gross margin	**907**	**(1,167)**	(178)%
Operating expenses:			
Research and development	$ 28,156	$ 25,842	9.0 %
General and administrative	32,406	27,497	17.9 %
Sales and marketing	14,219	10,362	37.2 %
Total operating expenses	**74,781**	**63,701**	17.4 %
Loss from operations	**$ (73,874)**	**$ (64,868)**	13.9 %
Interest income	$ 761	$ 18	4,127.78 %
Other expense, net	(51)	(1)	5,000.00 %
Loss before provision for income taxes	**$ (73,164)**	**$ (64,851)**	12.8 %
Provision for income taxes	—	—	
Net loss and comprehensive loss	**$ (73,164)**	**$ (64,851)**	12.8 %

Sales

	Year Ended December 31,		Change	
	2022	**2021**	**Amount**	**%**
Device	$ 5,246	$ 715	$ 4,531	633.7 %
Service	1,568	781	787	100.8 %
Total sales	$ 6,814	$ 1,496	$ 5,318	355.5 %

Device sales increased by $4.5 million, or 633.7%, for the year ended December 31, 2022 compared to the year ended December 31, 2021. This increase was driven by an increase in the volume of device sales. In addition, in the first quarter of 2022, we have taken a pricing action by increasing the price of the device while lowering the price of the annual subscription. This pricing action resulted in higher device revenue per unit and lower service revenue per unit for sales under the subscription plus ownership model. In addition, revenue is typically recognized for sales of hardware devices where control of the product transfers to the customer upon shipment of goods. In the first quarter of 2023, we have taken an additional pricing action by further increasing the price of the device while lowering the price of the annual subscription. We expect this pricing action will result in higher device revenue per unit and lower service revenue per unit.

Service sales increased by $0.8 million, or 100.8%, for the year ended December 31, 2022 compared to the year ended December 31, 2021. This increase was driven by an increase in the volume of devices installed as generally all commercial systems installations generate service revenue. Service sales revenue is generally recognized over time as we are providing the customer with ongoing access to our resources throughout the subscription period. This type of revenue is recurring in nature and we expect will continue to grow as more devices are sold.

Cost of sales

	Year Ended December 31,		Change	
	2022	**2021**	**Amount**	**%**
Device	$ 4,231	$ 2,058	$ 2,173	105.6 %
Service	1,676	605	1,071	177.0 %
Total cost of sales	$ 5,907	$ 2,663	$ 3,244	121.8 %

Cost of device sales increased by $2.2 million, or 105.6%, for the year ended December 31, 2022 compared to the year ended December 31, 2021. This increase was driven primarily by increase in third-party manufacturing costs and higher labor cost as a result of increased volume of products sold and as a result of supply chain challenges. The increase is comprised of a $0.7 million increase in product hardware costs and a $1.4 million increase in labor cost as a result of the increase in the volume of products sold and manufacturing cost increases.

Cost of service sales increased by $1.1 million, for the year ended December 31, 2022 compared to the year ended December 31, 2021. This increase was driven primarily by an increase of $1.1 million in internal overhead and labor costs.

We expect cost of sales to continue to increase as additional products are sold and we continue to experience supply chain challenges.

Research and development

	2022	2021	Amount	%
Research and development	$ 28,156	$ 25,842	$ 2,314	9.0 %

Research and development expenses increased by $2.3 million, or 9.0%, for the year ended December 31, 2022 compared to the year ended December 31, 2021. This increase was driven primarily by an increase in personnel related costs of $3.8 million as a result of increased headcount, an increase in stock-based compensation expense of $0.8 million due to stock option and restricted stock unit awards granted, an increase related to restructuring and severance cost of $0.4 million, and an increase in consulting and outsource costs of $0.3 million, partially offset by grant fulfilments of which 10 baby cradles were provisioned and delivered to BMGF and the milestones for service deliverables such as installment and training were met and recorded as credits to research and development expenses of $2.6 million and a decrease in fabrication services of $0.4 million.

General and administrative

	Year Ended December 31,		Change	
	2022	2021	Amount	%
General and administrative	$ 32,406	$ 27,497	$ 4,909	17.9 %

General and administrative expenses increased by $4.9 million, or 17.9%, for the year ended December 31, 2022 compared to the year ended December 31, 2021. This increase was driven primarily by an increase in insurance cost due to operating as a public company of $3.0 million; an increase in stock-based compensation expense of $2.4 million when compared to the prior year, which was mainly driven by $2.5 million of expense related to the costs associated with RSU awards granted to our former CEO and $0.5 million related to incremental cost of repricing vested options, partially offset by a reversal of $1.1 million related to an earnout expense for our former CEO; an increase in personnel related expenses of $0.8 million due to increased headcount; an increase in accounting and compliance related fees of $1.2 million; an increase in technology and subscription related costs of $0.8 million; an increase related to restructuring and severance cost of $0.6 million; and an increase in recruitment cost $0.5 million; partially offset by a decrease of $3.9 million in professional costs related to cost of outsourced accounting and financial reporting as compared to 2021.

Sales and marketing

	Year Ended December 31,		Change	
	2022	2021	Amount	%
Sales and marketing	$ 14,219	$ 10,362	$ 3,857	37.2 %

Sales and marketing expenses increased by $3.9 million, or 37.2%, for the year ended December 31, 2022 compared to the year ended December 31, 2021. This increase was driven primarily by an increase in personnel related expenses of $3.7 million due to increased headcount, an increase in stock-based compensation expense of $0.3 million due to stock option and restricted stock unit awards granted, and an increase in travel expense of $0.8 million, partially offset by a decrease in marketing expenses of $1.0 million related to trade shows, digital marketing and advertising.

Interest income

	Year Ended December 31,		Change	
	2022	2021	Amount	%
Interest income	$ 761	$ 18	$ 743	4,128 %

Interest income increased by $0.7 million, for the year ended December 31, 2022 compared to the year ended December 31, 2021. The increase was driven primarily by higher average cash balances and higher interest rates during the year ended December 31, 2022 compared to the year ended December 31, 2021.

Other expense, net

	Year Ended December 31,		Change	
	2022	2021	Amount	%
Other expense, net	$ (51)	$ (1)	$ (50)	5,000%

Other expense, net had an unfavorable increase in other expense by $50 thousand for the year ended December 31, 2022 compared to the year ended December 31, 2021. This unfavorable increase in other expense was driven primarily by realized loss on foreign currencies.

Liquidity and Capital Resources

We have funded our operations primarily with proceeds from the issuance of common and preferred stock. We have incurred significant cash burn and recurring net losses, which includes a net loss of $73.2 million for the year ended December 31, 2022, and an accumulated deficit of $209.5 million as of December 31, 2022. In December 2021, we completed the Business Combination with HealthCor, and as a result we received gross proceeds of approximately $162.1 million and net proceeds of approximately $141.5 million. As of December 31, 2022, we had cash and cash equivalents of $117.5 million. As we continue to invest in research and development of our products and sales and marketing, we expect to continue to incur a significant cash burn and recurring net losses for the foreseeable future until such time that our product and services sales generate enough gross profit to cover our operating expenses. However, we can provide no assurance that our product and service sales will generate a net profit in the future or that our cash resources will be sufficient to continue our commercialization and development activities.

Our ability to access capital when needed is not assured and, if capital is not available when, and in the amounts needed, we could be required to delay, scale back or abandon some or all of our development programs, commercialization of our products, and other operations which could materially harm our operations, financial condition and operating results. We expect that our existing cash and cash equivalents, together with proceeds from the sales of our products and services, will enable us to conduct our planned operations for at least the next 12 months. Factors that could accelerate cash needs include: (i) delays in achieving scientific and technical milestones; (ii) unforeseen capital expenditures and fabrication costs related to manufacturing; (iii) changes we may make in our business or commercialization and hiring strategy; (iv) the impact of the COVID-19 pandemic; (v) costs of running a public company; (vi) higher inflation and increases in product transportation and labor costs; and (vii) other items affecting our forecasted level of expenditures and use of cash resources including potential acquisitions. As part of the prioritization of our projects and expenditures, in December 2022, we suspended the development of our brain sensing platform, which was in the early stages of development to non-invasively measure key vital signs in the brain.

We expect to use our funds to further invest in the development of our products and services, commercial expansion, and for working capital and general corporate purposes.

Our future cash requirements will depend on many factors, including market acceptance of our products, the cost and timing of establishing additional sales, marketing and distribution capabilities; the cost of our research and development activities; our ability to enter into and maintain collaborations; the cost and timing of potential future regulatory clearances or approvals for our products; and the effect of competing technological and market developments. We cannot assure you that we will be able to obtain additional funds on acceptable terms, or at all. If we raise additional funds by issuing equity or equity-linked securities, our stockholders may experience dilution. Future debt financing, if available, may involve covenants restricting our operations or our ability to incur additional debt. Any debt or equity financing that we raise may contain terms that are not favorable to us or our stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish some rights to our technologies or our products, or grant licenses on terms that are not favorable to us. If we do not have or are not able to obtain sufficient funds, we may have to delay development or commercialization of our products. We also may have to reduce marketing, customer support or other resources devoted to our products or cease operations.

Cash

As of December 31, 2022, we had cash and cash equivalents of $117.5 million. Our future capital requirements may vary from those currently planned and will depend on various factors including further development costs, commercialization strategy, regulatory developments, supply constraints, manufacturing costs and international expansion. If we need additional funds and are unable to obtain funding on a timely basis, we may need to curtail significantly our product development and commercialization efforts to provide sufficient funds to continue our operations, which could adversely affect our business prospects.

Cash flows

The following table summarizes our cash flows for the periods indicated:

	Year Ended December 31,	
(In thousands)	**2022**	**2021**
Net cash used in operating activities	$ (72,339)	$ (47,182)
Net cash used in investing activities	(585)	(2,711)
Net cash provided by financing activities	7	176,767
Net (decrease) increase in cash and cash equivalents and restricted cash	**$ (72,917)**	**$ 126,874**

Net cash used in operating activities

For the year ended December 31, 2022, net cash used in operating activities of $72.3 million was due primarily to a net loss of $73.2 million, non-cash items of $11.8 million and changes in operating assets and liabilities of $10.9 million. Non-cash items were primarily stock based compensation expense of $10.7 million, including $0.1 million of stock-based compensation related to severance, and $0.1 million fixed asset impairment costs and other related restructuring costs. Changes in operating assets and liabilities were driven primarily by a decrease in accrued expenses and other current liabilities of $2.2 million, a decrease in due to related parties of $2.0 million, a decrease in deferred grant funding of $1.9 million, an increase in prepaid expenses and other current assets of $1.8 million, a decrease in accounts payable of $1.6 million, an increase in accounts receivables of $1.6 million, an increase in other long term assets of $0.6 million, an increase in unbilled receivables of $0.4 million, an increase in inventory of $0.3 million, and an increase in prepaid inventory of $0.3 million, partially offset by an increase in deferred revenue of $1.7 million.

For the year ended December 31, 2021, net cash used in operating activities of $47.2 million was due primarily to a net loss of $64.9 million, non-cash items of $8.7 million and changes in operating assets and liabilities of $9.0 million. Non-cash items were primarily stock-based compensation expense of $6.9 million. Changes in operating assets and liabilities were driven primarily by an increase in inventory of $2.7 million, partially offset by an increase in accrued expense and other current liabilities of $6.9 million and amounts due to related parties of $1.8 million.

Net cash used for investing activities

For the year ended December 31, 2022, net cash used in investing activities of $0.6 million was from fixed assets purchased.

For the year ended December 31, 2021, net cash used in investing activities of $2.7 million was from fixed assets purchased.

Net cash provided by financing activities

For the year ended December 31, 2022, net cash provided by financing activities of $7 thousand was proceeds from option exercises.

For the year ended December 31, 2021, net cash provided by financing activities of $176.8 million was primarily due to proceeds from issuance of Series D convertible preferred stock of $30.5 million, and net proceed from equity infusion from the Business Combination of $141.5 million.

Contractual obligations

In April 2020, we received a $1.6 million grant from the BMGF for the provision and equipping of 20 sites with our portable point-of-care MRI system to enable the performance of a multi-site study focused on optimizing diagnostic image quality. During the third quarter of 2021, we were awarded an additional $3.3 million grant, of which we received $2.5 million from the BMGF in September 2021 and the remaining amount of $0.8 million in second quarter of 2022. Refer to Note 14 in the notes to our combined and consolidated financial statements for the years ended December 31, 2022 and 2021 included elsewhere in this Annual Report on Form 10-K for a discussion of the BMGF grant. Any grant funds, plus any income, that have not been used for, or committed to, the project must be returned promptly to BMGF upon expiration of or termination of the agreement. Both of the grants are designed to support the deployment of a total of 25 Swoop® system devices and other services to investigators, which commenced in the spring of 2021, and is expected to fund the program for approximately two years. At December 31, 2022, 20 Swoop® system units and 10 baby cradles were provisioned and delivered to BMGF and a majority of the milestones for service deliverables were also met. These grants are designed to provide data to validate the use of our Swoop® system in measuring the impact of maternal anemia, malnutrition, infection and birth related injury.

We had no other significant contractual obligations as of December 31, 2022.

For information on contingencies, refer to Note 14 to our combined and consolidated financial statements and notes thereto for the years ended December 31, 2022 and 2021 included elsewhere in this Annual Report on Form 10-K.

Critical Accounting Estimates

Our financial statements are prepared in accordance with accounting principles generally accepted in the United States of America (“U.S. GAAP”). The preparation of our financial statements in conformity with U.S. GAAP requires us to make estimates and assumptions that affect certain reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. While our significant accounting policies are described in more detail in Note 2 in our combined and consolidated financial statements for the years ended December 31, 2022 and 2021 included elsewhere in this Annual Report on Form 10-K, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our financial statements.

Revenue recognition

We make judgments including determination of the timing and pattern of satisfaction of performance obligations, determination of the standalone selling price (“SSP”) of performance obligations and estimation of variable consideration if any. We offer alternative payment structures and “as-a-service” offerings that are assessed to determine whether an embedded lease arrangement exists. We account for those contracts as a lease arrangement under ASC 842 and ASC 840, Leases for the years ended December 31, 2022 and 2021, respectively. We identify certain Device-as-a-Service contracts to be within the scope of ASC 842 and ASC 606. Upon adoption of ASC 842 revenue from contracts with customers, in which we act as a lessor. For contracts that are in the scope of both ASC 842 and ASC 606, and in which the lease component is an operating lease, we apply the practical expedient in ASC 842 to combine the lease component (the device itself in device as a service, ("DaaS") contracts) and non-lease (maintenance and SaaS) components, and to account for the combined components as a single lease component. Accordingly, we account for the monthly payments as lease revenue. For contracts in which the lease component is a sales-type lease, we derecognize the asset (the MRI device) and recognize a lease receivable in an amount that represents the present value of the lease payments.

Inventories

Inventories primarily consist of finished goods which are produced by our third-party contract manufacturers and raw materials ordered in advance by the third-party contract manufacturer due to long delivery-lead time and were billed to the Company. Inventories are stated at the lower of actual cost, determined using the average cost method, or net realizable value (“NRV”). We routinely evaluate quantities and value of our inventories in light of current market conditions and market trends and record a write-down against the cost of inventories for NRV below cost. NRV is based upon an estimated average selling price reduced by the estimated costs of disposal and transportation. The determination of NRV involves numerous judgments including estimating selling prices, existing customer orders, and estimated costs of disposal and transportation. If actual market conditions differ from our estimates, future results of operations could be materially affected.

The valuation of inventory also requires us to estimate excess and obsolete inventory. We periodically review the age, condition and turnover of our inventory to determine whether any inventory has become obsolete or has declined in value and incur a charge to operations for known and anticipated inventory obsolescence. We also consider how quickly customers will transition from older products to newer products, including whether older products can be re-manufactured into new products. The evaluation takes into consideration the effect that new products might have on the sale of existing products, product obsolescence, product merchantability and other factors. Market conditions are subject to change and if actual market conditions are less favorable than those projected by management, additional inventory write-downs may be required, which would have a negative impact on gross margin.

Stock-based compensation

Our stock-based compensation program includes restricted stock unit and stock option grants to our employees, directors and consultants. Stock options are granted at exercise prices not less than the estimated fair market value of our common stock at the dates of grant. For purposes of restricted stock unit grants, the grant date fair value is calculated as the fair market value of the stock on the date of grant.

The fair values of stock option grants are estimated using a Black-Scholes option-pricing model. Key inputs and assumptions include the expected term of the option, stock price volatility, risk free interest rate, dividend yield, stock price and exercise price. Many of the assumptions require significant judgment and changes in assumptions could have a significant impact in the determination of stock-based compensation expense.

Key assumptions include:

- Risk free interest rate: The risk free interest rate for the expected term of the awards is based on the U.S. Treasury yield curve in effect at the time of the grant.
- Expected dividend yield: We have never declared or paid any cash dividends and do not expect to pay any cash dividends in the foreseeable future.
- Expected term: We calculate expected term using the “simplified” method, which is the simple average of the vesting period and the contractual term. The simplified method is applied as we do not have sufficient historical data to provide a reasonable basis for an estimate of the expected term. We calculate the expected term for employee and non-employee directors awards that take into account the effects of expected employee or non-employee director exercise and post-vesting employment termination behavior.
- Expected volatility: We determined expected annual volatility based on the historical stock volatility of a group of similar companies that are publicly traded over a period equivalent to the expected term of the stock-based awards.

Generally, stock options granted to employees fully vest four years from the grant date and have a contractual term of 10 years and stock options granted to non-employees fully vest one year from the grant date or upon performance of a service and have a contractual term of 10 years.

During the year ended December 31, 2020, Liminal was a wholly owned subsidiary of 4Bionics, and as such, 4Bionics granted equity awards in the form of incentive units to Liminal employees and nonemployees under 4Bionics’ stock-based compensation program. On April 2, 2021, 4Bionics executed a plan of liquidation and dissolution and its ownership in Liminal was distributed to its members and to the holders of incentive units. Immediately subsequent to the dissolution, all outstanding unvested incentive unit awards under 4Bionics’ 2019 Equity Incentive Plan were replaced with preferred stock awards indexed to and settled in the preferred stock of the former 4Bionics subsidiaries Liminal, Detect, Inc. (f/k/a Homodeus Inc.), identifeye HEALTH Inc. (f/k/a Tesseract Health, Inc.) and Protein Evolution, Inc. The preferred stock awards were subject to service vesting conditions only. No incremental value was provided to participants as a result of the modification of the awards as the modification date fair value of the incentive unit awards was equal to the modification date fair value of the stock underlying the restricted stock awards. Moreover, the remaining vesting period before and after the modification was unchanged. No incremental compensation expense was recognized as a result of the modification.

Prior to the dissolution of 4Bionics, a portion of total 4Bionics stock-based compensation expense was allocated to Liminal based on the level of service provided by the relevant employees and nonemployees to Liminal over the term of the award. Subsequent to the dissolution of 4Bionics, we recognize the stock-based compensation expense related to the replacement preferred stock awards and no allocation methodology is required. In connection with the Closing of the Business Combination, all replacement preferred stock awards were accelerated to fully vest.

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2 to our combined and consolidated financial statements and notes thereto for the years ended December 31, 2022 and 2021 included elsewhere in this Annual Report on Form 10-K.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risk in the ordinary course of business. Market risk represents the risk of loss that may impact our results of operations or financial position due to adverse changes in financial market prices and rates. Our market risk exposure is primarily a result of fluctuations in interest rates, inflation risk, and foreign exchange risk. We do not hold, issue or enter into any financial instruments for speculative or trading purposes. We do not have significant exposure to foreign currencies.

Interest rate risk

Our cash equivalents as of December 31, 2022 consisted of $63.4 million in money market funds. Such interest-earning instruments carry a degree of interest rate risk. The goals of our investment policy are liquidity and capital preservation. We believe that we do not have any material exposure to changes in the fair value of these assets as a result of changes in interest rates due to the short-term nature of our cash equivalents. Based on our balance sheet position at December 31, 2022, the annualized effect of a 0.5 percentage point decrease in interest rates would be to decrease earnings before income taxes by $0.3 million.

Inflation Risk

Inflation has continued to increase during 2022 and is expected to continue to increase for the near future. We rely on a single contract manufacturer; inflation generally affects us by increasing our cost of manufacturing and a higher cost of certain key components. To the extent our costs are impacted by general inflationary pressures, we may not be able to fully offset such higher costs through price increases or manufacturing efficiencies. Our inability or failure to do so could harm our business, financial condition, and results of operations.

Foreign Exchange Risk

We operate our business primarily within the United States. With respect to our sales outside the U.S., the majority of our transactions are executed in U.S. dollars and, to a lesser extent, in foreign currency. We have not utilized hedging strategies with respect to such foreign exchange exposure. This limited foreign currency translation risk is not expected to have a material impact on our combined and consolidated financial statements.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

See financial statements included in Item 15 "Exhibits and Financial Statement Schedules" of this Annual Report on Form 10-K.

Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not applicable.

Item 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our principal executive officer and principal financial officer evaluated the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) as of December 31, 2022. Based upon that evaluation, our principal executive officer and principal financial officer concluded that, as of December 31, 2022, solely due to the material weaknesses in our internal control over financial reporting discussed below, our disclosure controls and procedures were not effective at the reasonable assurance level to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms, and is accumulated and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate, to allow timely decisions regarding required disclosure.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act, as a process designed by, or under the supervision of, our principal executive and principal financial officers and effected by our board of directors, management and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Our internal control over financial reporting includes those policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2022 and, in making this assessment, used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework (2013 framework). Because of the material weaknesses described below, our management believes that, as of December 31, 2022, our internal control over financial reporting was not effective based on those criteria.

Material Weakness in Internal Control Over Financial Reporting

We have identified two material weaknesses in our internal control over financial reporting. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis.

As previously disclosed, prior to the Closing of the Business Combination in December 2021, Legacy Hyperfine and Liminal were private companies and had limited accounting and financial reporting personnel and other resources with which to address its internal controls and procedures. We outsourced our accounting and financial reporting to 4Catalyzer Corporation ("4Catalyzer") and did not have our own finance function to appropriately perform the supervision and review of the information received from 4Catalyzer and assess its reasonableness and accuracy. As a result, in connection with the combined financial statement close process of Legacy Hyperfine and Liminal for the years ended December 31, 2020 and 2019, we identified a material weakness in our internal control over financial reporting.

In addition, as previously disclosed, HealthCor previously recorded a portion of its Class A ordinary shares subject to possible redemption in permanent equity. Notwithstanding the presence of maximum redemption thresholds or charter provisions common in SPACs that provide a limitation on redemptions that would cause a SPAC's net tangible assets to be less than $5,000,001, in accordance with SEC Staff guidance on redeemable equity instruments, ASC 480-10-S99, "Distinguishing Liabilities from Equity", and EITF Topic D-98, "Classification and Measurement of Redeemable Securities", and, according to SEC Staff communications with certain independent auditors, redemption provisions not solely within the control of the issuing company require ordinary shares subject to redemption to be classified outside of permanent equity. Although we did not specify a maximum redemption threshold in HealthCor's Amended and Restated Memorandum and Articles of Association (the "HealthCor Articles"), the HealthCor Articles provided that we could not redeem our public shares in an amount that would cause our net tangible assets to be less than $5,000,001. In light of the SEC Staff communications with certain independent auditors, our management re-evaluated the effectiveness of our disclosure controls and procedures, and based upon that evaluation, we concluded that the misclassification of the Class A ordinary shares was quantitatively material to individual line items within the balance sheet. This resulted in a restatement of the initial carrying value of the Class A ordinary shares subject to possible redemption, with the offset recorded to additional paid-in capital (to the extent available), accumulated deficit and ordinary shares. We concluded that the foregoing represents a material weakness in our internal controls over financial reporting.

Notwithstanding these material weaknesses, management has concluded that our audited combined and consolidated financial statements included in this Annual Report on Form 10-K are fairly stated in all material respects in accordance with U.S. GAAP for each of the periods presented therein.

Plan for Remediation of the Material Weaknesses in Internal Control Over Financial Reporting

In response to these material weaknesses, our management has expended, and will continue to expend, a substantial amount of effort and resources for the remediation of material weaknesses in internal control over financial reporting. Our management developed and continues to execute a remediation plan, which included the hiring of accounting and finance resources including the Chief Financial Officer and Vice President, Controller with technical public company accounting and financial reporting experience, as well as other team members. We also have access to accounting training, literature, research materials and increased communication among our personnel and outsourced third-party professionals with whom we may consult regarding the application of complex accounting transactions. Our remediation plan can only be accomplished over time and will be continually reviewed to determine that we are achieving our objectives. We believe these actions will be sufficient to remediate the identified material weaknesses and strengthen our internal control over financial reporting; however, there is no assurance that these initiatives will ultimately have the intended effects. The material weaknesses will not be considered remediated until our management has designed and implemented effective controls that operate for a sufficient period of time and our management has concluded through testing that these controls are effective. We plan to continue to devote significant time and attention to continue to remediate the above material weaknesses as soon as reasonably practicable.

Changes in Internal Controls

Other than the changes made to remediate the material weaknesses described above, there were no changes in our internal control over financial reporting, identified in connection with the evaluation of such internal control that occurred during the fourth quarter ended December 31, 2022, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. OTHER INFORMATION

The information in the section entitled, "Exclusive License Agreements with The General Hospital Corporation (d/b/a Massachusetts General Hospital)" in Item 1. Business of this report is incorporated herein by reference.

Item 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The response to this item is incorporated by reference from the discussion responsive thereto under the headings “Management and Corporate Governance,” “Delinquent Section 16(a) Reports” and “Code of Conduct and Ethics” in our proxy statement for the 2023 annual meeting of stockholders (the “2023 Proxy Statement”).

Item 11. EXECUTIVE COMPENSATION

The response to this item is incorporated by reference from the discussion responsive thereto under the heading “Executive Compensation” in our 2023 Proxy Statement.

Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The response to this item is incorporated by reference from the discussion responsive thereto under the headings “Security Ownership of Certain Beneficial Owners and Management” and “Equity Compensation Plan Information” in our 2023 Proxy Statement.

Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The response to this item is incorporated by reference from the discussion responsive thereto under the headings “Certain Relationships and Related Person Transactions” and “Management and Corporate Governance” in our 2023 Proxy Statement.

Item 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The response to this item is incorporated by reference from the discussion responsive thereto under the heading “Ratification of Appointment of Independent Registered Public Accounting Firm” in our 2023 Proxy Statement.

PART IV

Item 15. **EXHIBITS, FINANCIAL STATEMENT SCHEDULES**

Item 15(a)(1) **Index to Audited Combined and Consolidated Financial Statements as of December 31, 2022 and 2021 and for the years ended December 31, 2022 and 2021**

Item 15(a)(2) Financial statement schedules have not been included because they are not applicable or the information is included in the financial statements or notes thereto.

Item 15(a)(3) Exhibits

The following is a list of exhibits filed as part of this Annual Report on Form 10-K.

Exhibit Number	Exhibit Description	Filed Herewith	Incorporated by Reference Herein from Form or Schedule	Filing Date	SEC File/ Reg. Number
2.1†	Business Combination Agreement, dated as of July 7, 2021, by and among Hyperfine, Inc. (formerly HealthCor Catalio Acquisition Corp.), Optimus Merger Sub I, Inc., Optimus Merger Sub II, Inc., Hyperfine Operations, Inc. (formerly Hyperfine, Inc.) and Liminal Sciences, Inc.		Form 8-K (Exhibit 2.1)	7/8/2021	001-39949
3.1	Certificate of Incorporation of Hyperfine, Inc., as amended		Form 8-K (Exhibit 3.1)	12/28/2021	001-39949
3.2	Bylaws of Hyperfine, Inc.		Form 8-K (Exhibit 3.2)	12/28/2021	001-39949
4.1	Specimen Class A Common Stock Certificate		Form S-4/A (Exhibit 4.2)	9/29/2021	333-259148
4.2	Description of Securities	X			
10.1	Form of PIPE Investor Subscription Agreement for institutional investors, dated as of July 7, 2021, by and between Hyperfine, Inc. (formerly HealthCor Catalio Acquisition Corp.) and the subscriber parties thereto		Form 8-K (Exhibit 10.1)	7/8/2021	001-39949
10.2	Form of PIPE Investor Subscription Agreement for individual investors, dated as of July 7, 2021, by and between Hyperfine, Inc. (formerly HealthCor Catalio Acquisition Corp.) and the subscriber parties thereto		Form 8-K (Exhibit 10.2)	7/8/2021	001-39949
10.3	Transaction Support Agreement, dated as of July 8, 2021, by and among Hyperfine, Inc. (formerly HealthCor Catalio Acquisition Corp.), Dr. Jonathan M. Rothberg, and certain supporting stockholders of Hyperfine Operations, Inc. (formerly Hyperfine, Inc.) and Liminal Sciences, Inc. affiliated with Dr. Rothberg		Form 8-K (Exhibit 10.1)	7/8/2021	001-39949

10.4	Sponsor Letter Agreement, dated as of July 7, 2021, by and among Hyperfine, Inc. (formerly HealthCor Catalio Acquisition Corp.), Hyperfine Operations, Inc. (formerly Hyperfine, Inc.), Liminal Sciences, Inc., HC Sponsor LLC, and the other stockholders party thereto	Form 8-K (Exhibit 10.3)	7/8/2021	001-39949
10.5+	Offer Letter, dated as of October 4, 2022, by and between Hyperfine, Inc. and Maria Sainz	Form 8-K (Exhibit 10.1)	10/6/2022	001-39949
10.6+	Offer Letter, dated as of February 2, 2023, by and between Hyperfine, Inc. and Brett Hale	Form 8-K (Exhibit 10.1)	2/8/2023	001-39949
10.7+	Letter Agreement, dated as of June 29, 2022, by and between Hyperfine, Inc. and David Scott	Form 8-K (Exhibit 10.1)	6/29/2022	001-39949
10.8+	Amended and Restated Offer Letter, dated as of August 27, 2021, by and between Hyperfine Operations, Inc. (formerly Hyperfine, Inc.) and Alok Gupta	Form S-4 (Exhibit 10.11)	8/30/2021	333-259148
10.9+	Offer Letter, dated as of January 4, 2020, by and between Hyperfine Operations, Inc. (formerly Hyperfine, Inc.) and Khan Siddiqui, M.D.	Form S-4 (Exhibit 10.13)	8/30/2021	333-259148
10.10+	Separation Agreement, dated as of February 6, 2023, by and between Hyperfine, Inc. and Neela Paykel	Form 8-K (Exhibit 10.3)	2/8/2023	001-39949
10.11+	Executive Severance Plan, as amended	Form 8-K (Exhibit 10.2)	2/8/2023	001-39949
10.12	Technology and Services Exchange Agreement, dated as of November 19, 2020, by and among Butterfly Network, Inc., Hyperfine Operations, Inc. (formerly Hyperfine, Inc.), Liminal Sciences, Inc. and the other participants named therein	Form S-4 (Exhibit 10.17)	8/30/2021	333-259148
10.13	Technology and Services Exchange Agreement, dated as of February 17, 2021, by and among Quantum-Si Incorporated, Hyperfine Operations, Inc. (formerly Hyperfine, Inc.), Liminal Sciences, Inc. and the other participants named therein	Form S-4 (Exhibit 10.18)	8/30/2021	333-259148
10.14	Technology and Services Exchange Agreement, dated as of July 7, 2021, by and among Hyperfine Operations, Inc. (formerly Hyperfine, Inc.), Liminal Sciences, Inc. and the participants named therein	Form 8-K (Exhibit 10.16)	12/28/2021	001-39949
10.15@	License Agreement, dated as of May 29, 2014, by and between Hyperfine Operations, Inc. (formerly Hyperfine, Inc.) and The General Hospital Corporation, d/b/a Massachusetts General Hospital.	Form S-4 (Exhibit 10.8)	8/30/2021	333-259148
10.16@	Manufacture and Supply Agreement, dated as of October 15, 2018, by and between Hyperfine, Inc. and Benchmark Electronics, Inc.	Form S-4 (Exhibit 10.10)	8/30/2021	333-259148
10.17.1+	Hyperfine, Inc. 2021 Equity Incentive Plan	Form 8-K (Exhibit 10.20.1)	12/28/2021	001-39949
10.17.2+	Form of Stock Option Agreement under 2021 Equity Incentive Plan	Form 8-K (Exhibit 10.20.2)	12/28/2021	001-39949

10.17.3+	Form of Restricted Stock Unit Agreement under 2021 Equity Incentive Plan		Form S-8 (Exhibit 99.3)	3/28/2022	333-263897
10.18.1+	Hyperfine Operations, Inc. (formerly Hyperfine, Inc.) 2014 Employee, Director and Consultant Equity Incentive Plan, as amended		Form 8-K (Exhibit 10.21.1)	12/28/2021	001-39949
10.18.2+	Form of Stock Option Agreement under Hyperfine Operations, Inc. (formerly Hyperfine, Inc.) 2014 Employee, Director and Consultant Equity Incentive Plan, as amended		Form 8-K (Exhibit 10.21.2)	12/28/2021	001-39949
10.19.1+	Liminal Sciences, Inc. 2021 Employee, Director and Consultant Equity Incentive Plan, as amended		Form 8-K (Exhibit 10.22.1)	12/28/2021	001-39949
10.19.2+	Form of Stock Option Agreement under Liminal Sciences, Inc. 2021 Employee, Director and Consultant Equity Incentive Plan, as amended		Form 8-K (Exhibit 10.22.2)	12/28/2021	001-39949
10.20+	Nonemployee Director Compensation Policy		Form 8-K (Exhibit 10.23)	12/28/2021	001-39949
10.21+	Form of Indemnification Agreement		Form 8-K (Exhibit 10.24)	12/28/2021	001-39949
10.22+	Form of Indemnity Agreement of HealthCor		Form S-1 (Exhibit 10.4)	1/8/2021	333-252002
10.23	Amended and Restated Registration Rights Agreement, dated as of December 22, 2021, by and among Hyperfine, Inc. (formerly HealthCor Catalio Acquisition Corp.), HC Sponsor LLC and certain other security holders		Form 10-Q (Exhibit 10.1)	8/11/2022	001-39949
10.24	Forfeiture Agreement, dated as of December 21, 2021, by and among Hyperfine, Inc. (formerly HealthCor Catalio Acquisition Corp.), HC Sponsor LLC, Hyperfine Operations, Inc. (formerly Hyperfine, Inc.) and Liminal Sciences, Inc.		Form 8-K (Exhibit 10.27)	12/28/2021	001-39949
10.25+	Inducement Non-Qualified Stock Option Agreement, dated as of February 13, 2023, by and between the Registrant and Brett Hale.	X			
21.1	List of Subsidiaries		Form 10-K (Exhibit 21.1)	3/25/2022	001-39949
23.1	Consent of Deloitte & Touche LLP	X			
31.1	Certification of the Chief Executive Officer	X			
31.2	Certification of the Chief Financial Officer	X			
32	Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	X			
101.INS	Inline XBRL Instance Document	X			
101.SCH	Inline XBRL Taxonomy Extension Schema Document	X			
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document	X			
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document	X			

101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document	X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document	X
104	Cover Page Interactive Date File (formatted as Inline XBRL and contained in Exhibit 101)	X

† Certain of the exhibits and schedules to this Exhibit have been omitted in accordance with Regulation S-K Item 601(a)(5). The Registrant agrees to furnish a copy of all omitted exhibits and schedules to the SEC upon its request.

+ Management contract or compensatory plan or arrangement.

@ Certain confidential portions of this Exhibit were omitted by means of marking such portions with brackets ("[***]") because the identified confidential portions (i) are not material and (ii) is the type of information that the Company treats as private or confidential.

* The certification attached as Exhibit 32 that accompanies this Annual Report on Form 10-K is not deemed filed with the SEC and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Form 10-K, irrespective of any general incorporation language contained in such filing.

Item 16. FORM 10-K SUMMARY

Not applicable.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

HYPERFINE, INC.

Date: March 22, 2023

By: /s/ Maria Sainz
Maria Sainz
President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signatures		Title	Date
By:	/s/ Maria Sainz Maria Sainz	President, Chief Executive Officer and Director (principal executive officer)	March 22, 2023
By:	/s/ Alok Gupta Alok Gupta	Chief Financial Officer (principal financial officer and principal accounting officer)	March 22, 2023
By:	/s/ R. Scott Huennekens R. Scott Huennekens	Executive Chairperson of the Board	March 22, 2023
By:	/s/ Jonathan M. Rothberg, Ph.D. Jonathan M. Rothberg, Ph.D.	Vice Chairperson of the Board	March 22, 2023
By:	/s/ John Dahldorf John Dahldorf	Director	March 22, 2023
By:	/s/ Ruth Fattori Ruth Fattori	Director	March 22, 2023
By:	/s/ Daniel J. Wolterman Daniel J. Wolterman	Director	March 22, 2023

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the stockholders and the Board of Directors of Hyperfine, Inc.

Opinion on the Financial Statements

We have audited the accompanying combined and consolidated balance sheets of Hyperfine, Inc. and subsidiaries, (the "Company") as of December 31, 2022 and 2021, the related combined and consolidated statements of operations and comprehensive loss, changes in convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the two years in the period ended December 31, 2022, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2022, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Deloitte & Touche LLP

New York City, New York
March 22, 2023
We have served as the Company's auditor since 2021.

HYPERFINE, INC. AND SUBSIDIARIES

COMBINED AND CONSOLIDATED BALANCE SHEETS
AS OF DECEMBER 31, 2022 AND 2021
(in thousands, except share and per share amounts)

	December 31,	
	2022	**2021**
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 117,472	$ 188,498
Restricted cash	771	2,662
Accounts receivable, less allowance of $180 and $32 in 2022 and 2021, respectively	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 (NOTE 14)		
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 2021, respectively	5	5
Class B Common stock, $.0001 par value; 27,000,000 shares authorized; 15,055,288 shares issued and outstanding at December 31, 2022 and 2021	2	2
Additional paid-in capital	333,199	322,540
Accumulated deficit	(209,484)	(136,320)
Total stockholders' equity	**$ 123,722**	**$ 186,227**
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 134,051**	**$ 202,473**

The accompanying notes are an integral part of these combined and consolidated financial statements.

HYPERFINE, INC. AND SUBSIDIARIES

COMBINED AND CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
FOR THE YEARS ENDED DECEMBER 31, 2022 AND 2021
(in thousands, except share and per share amounts)

	Year ended December 31,	
	2022	**2021**
Sales		
Device	$ 5,246	$ 715
Service	1,568	781
Total sales	$ 6,814	$ 1,496
Cost of sales		
Device	$ 4,231	$ 2,058
Service	1,676	605
Total cost of sales	$ 5,907	$ 2,663
Gross margin	**907**	**(1,167)**
Operating Expenses:		
Research and development	$ 28,156	$ 25,842
General and administrative	32,406	27,497
Sales and marketing	14,219	10,362
Total operating expenses	**74,781**	**63,701**
Loss from operations	**$ (73,874)**	**$ (64,868)**
Interest income	$ 761	$ 18
Other expense, net	(51)	(1)
Loss before provision for income taxes	**$ (73,164)**	**$ (64,851)**
Provision for income taxes	—	—
Net loss and comprehensive loss	**$ (73,164)**	**$ (64,851)**
Net loss per common share attributable to common stockholders, basic and diluted	$ (1.04)	$ (17.57)
Weighted-average shares used to compute net loss per share attributable to common stockholders, basic and diluted	70,449,191	3,690,523

The accompanying notes are an integral part of these combined and consolidated financial statements.

HYPERFINE, INC. AND SUBSIDIARIES

COMBINED AND CONSOLIDATED STATEMENTS OF CHANGES IN CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)

FOR THE YEARS ENDED DECEMBER 31, 2022 AND 2021

(in thousands, except share amounts)

	Hyperfine Convertible Preferred Stock		Liminal Convertible Preferred Stock		Class A Common Stock		Class B Common Stock		Additional	Accumulated	Total Shareholders'
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Paid-in Capital	Deficit	Equity (Deficit)
Balance, December 31, 2020	**95,010,858**	**$ 128,286**	**—**	**$ —**	**1,576,137**	**$ —**	**—**	**$ —**	**$ 10,415**	**$ (71,469)**	**$ (61,054)**
Net loss	—	—	—	—	—	—	—	—	—	(64,851)	(64,851)
Issuance of Series D convertible preferred stock, net of issuance costs	14,171,333	30,461	—	—	—	—	—	—	—	—	—
Investment from 4Bionics, LLC	—	—	—	—	—	—	—	—	3,516	—	3,516
Conversion of Liminal Common stock	—	—	57,500,000	9,350	(180)	—	—	—	(9,350)	—	(9,350)
Exercise of stock options	—	—	—	—	565,533	—	—	—	1,497	—	1,497
Conversion of the convertible preferred stock into Class A and Class B common stock at the Business Combination	(109,182,191)	(158,747)	(57,500,000)	(9,350)	31,028,815	3	15,055,288	2	168,092	—	168,097
Net equity infusion from the Business Combination	—	—	—	—	21,806,756	2	—	—	141,469	—	141,471
Issuance of Class A common stock to a service provider	—	—	—	—	300,000	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	—	—	6,901	—	6,901
Balance, December 31, 2021	**—**	**$ —**	**—**	**$ —**	**55,277,061**	**$ 5**	**15,055,288**	**$ 2**	**$ 322,540**	**$ (136,320)**	**$ 186,227**
Net loss	—	—	—	—	—	—	—	—	—	(73,164)	(73,164)
Issuance of restricted stock	—	—	—	—	319,557	—	—	—	—	—	—
Exercise of stock options	—	—	—	—	25,870	—	—	—	7	—	7
Stock-based compensation expense	—	—	—	—	—	—	—	—	10,652	—	10,652
Balance, December 31, 2022	**—**	**$ —**	**—**	**$ —**	**55,622,488**	**$ 5**	**15,055,288**	**$ 2**	**$ 333,199**	**$ (209,484)**	**$ 123,722**

The accompanying notes are an integral part of these combined and consolidated financial statements.

HYPERFINE, INC. AND SUBSIDIARIES

COMBINED AND CONSOLIDATED STATEMENTS OF CASH FLOWS
FOR THE YEARS ENDED DECEMBER 31, 2022 AND 2021
(in thousands)

	Year ended December 31,	
	2022	**2021**
Cash flows from operating activities:		
Net loss	$ (73,164)	$ (64,851)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	1,015	726
Stock-based compensation expense	10,652	6,901
Write-off of other assets - related party	—	984
Other	91	85
Changes in assets and liabilities		
Accounts receivable	(1,550)	(379)
Unbilled receivables	(363)	(91)
Inventory	(312)	(2,667)
Prepaid expenses and other current assets	(1,837)	(666)
Due from related parties	(34)	1,451
Other assets - related party	—	260
Prepaid inventory	(281)	—
Other long term assets	(632)	(1,201)
Accounts payable	(1,570)	1,436
Deferred grant funding	(1,891)	1,052
Deferred revenue	1,664	1,082
Due to related parties	(1,981)	1,845
Accrued expenses and other current liabilities	(2,146)	6,851
Net cash used in operating activities	**$ (72,339)**	**$ (47,182)**
Cash flows from investing activities:		
Purchases of property and equipment	(585)	(2,711)
Net cash used in investing activities	**$ (585)**	**$ (2,711)**
Cash flows from financing activities:		
Proceeds from exercise of stock options	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)
Investment from 4Bionics, LLC	—	3,516
Net proceeds from equity infusion from the Business Combination	—	141,471
Net cash provided by financing activities	**$ 7**	**$ 176,767**
Net (decrease) increase in cash and cash equivalents and restricted cash	**(72,917)**	**126,874**
Cash, cash equivalents and restricted cash, beginning of year	191,160	64,286
Cash, cash equivalents and restricted cash, end of year	**$ 118,243**	**$ 191,160**
Reconciliation of cash, cash equivalents, and restricted cash reported in the balance sheets		
Cash and cash equivalents	$ 117,472	$ 188,498
Restricted cash	771	2,662
Total cash, cash equivalents and restricted cash	**$ 118,243**	**$ 191,160**
Supplemental disclosure of cash flow information:		
Cash received from exchange of research and development tax credits	**$ 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**

The accompanying notes are an integral part of these combined and consolidated financial statements.

1. ORGANIZATION AND DESCRIPTION OF BUSINESS

Hyperfine, Inc. (together with its subsidiaries, as applicable, "Hyperfine" and the "Company"), formerly known as HealthCor Catalio Acquisition Corp. ("HealthCor"), was incorporated as a Cayman Islands exempted company on November 18, 2020. The Company's legal name became Hyperfine, Inc. in connection with the closing of the Business Combination (the "Closing") on December 22, 2021 (the "Closing Date"), as defined and described in Note 3. Business Combination. In connection with the Closing, Hyperfine, Inc., a Delaware corporation ("Legacy Hyperfine"), and Liminal Sciences, Inc., a Delaware corporation ("Liminal"), merged with and into separate wholly owned subsidiaries of HealthCor and became wholly-owned subsidiaries of the Company, and changed their names to Hyperfine Operations, Inc. and Liminal Operations, Inc., respectively. Liminal subsequently changed its name to Liminal Sciences, Inc. The prior period financial information represents the combined financial results of Legacy Hyperfine and Liminal.

The Company is an innovative digital health business with a mission to provide affordable and accessible imaging and monitoring through magnetic resonance imaging ("MRI") to revolutionize healthcare for people around the world. The Company's Swoop® Portable Magnetic Resonance ("MR") Imaging® System ("Swoop® system") produces high quality images at a lower magnetic field strength than conventional MRI scanners. Healthcare professionals can use the Swoop® system to make effective clinical diagnoses on a patient in various of settings where MRI devices have previously been inaccessible. The Company received 510(k) clearance from the U.S. Food and Drug Administration ("FDA") in 2020. The Swoop® system has since been authorized for brain imaging in several countries, including the European Union (CE marking), the United Kingdom (UK Conformity Assessment ("UKCA")), Canada, Australia, New Zealand and Pakistan. All of the Company's revenue to date has been generated from sales of this machine and related services. In December 2022, the Company has suspended its program to develop a device to non-invasively measure key vital signs in the brain. In addition to Legacy Hyperfine and Liminal, the Company has an indirect wholly-owned subsidiary in the United Kingdom that did not have any significant operations during 2022.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation and Principles of Consolidation

The accompanying combined and consolidated financial statements include the accounts of the Company and have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") and pursuant to the accounting disclosure rules and regulations of the Securities and Exchange Commission (the "SEC"). All intercompany transactions and balances have been eliminated.

COVID-19 Outbreak

In March 2020, the World Health Organization declared the global outbreak of COVID-19 to be a pandemic. The Company continues to closely monitor the recent COVID-19 developments, including the lifting of COVID-19 safety measures, the drop in COVID-19 vaccination rates, the implementation of, and reaction to, vaccine mandates, the spread of new strains or variants of the coronavirus, and supply chain and labor shortages. The COVID-19 pandemic has had, and is expected to continue to have, an adverse impact on our operations. For example, we have experienced restrictions on our salesforce's ability to visit sites. Many hospitals and other healthcare providers decreased spending and limited physical access to facilities, slowing the Company's ability to demonstrate its Swoop® system. Many hospitals and other healthcare providers have continued to focus their attention on addressing COVID-19, which the Company believes has resulted in lower sales volume. Trade shows and conferences moved to a virtual platform creating difficulty in demonstrating our device to key stakeholders. In addition, the Company's supplier and sub tier suppliers have been adversely affected by COVID-19 and the Company has also experienced increases in product costs as raw materials have been constrained.

In adjusting to the COVID-19 market and manufacturing conditions, the Company did not have to materially adjust its existing resource allocation or its factors of production. The Company has not incurred any significant impairment losses in the carrying values of its assets as a result of the COVID-19 pandemic and is not aware of any specific related event or circumstance that would require the Company to revise its estimates reflected in its combined and consolidated financial statements.

COVID-19 created multiple commercial challenges in 2022 and 2021 and the commercial challenges and restrictions from COVID-19 have been generally reduced in 2023, however, the Company is unable to predict the full impact that the COVID-19 pandemic will have on its future results of operations, liquidity and financial condition due to numerous uncertainties, including the duration of the pandemic, and the actions that may be taken by government authorities across the United States and elsewhere, it is not expected to result in any significant changes in costs going forward.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentration of credit risk consist principally of cash and cash equivalents. At December 31, 2022 and 2021, substantially all the Company's cash and cash equivalents were invested at three and two financial institutions, respectively. The Company also maintains balances in various operating accounts above federally insured limits. The Company has not experienced any losses on such accounts and does not believe it is exposed to any significant credit risk on cash and cash equivalents.

For the years ended December 31, 2022 and 2021 there was one customer that represented 10% or more of total net revenue. We had two customers as of December 31, 2022 and three customers as of December 31, 2021, respectively, that each accounted for more than 10% of our total accounts receivable, net and unbilled receivables.

The Company utilizes a single exclusive manufacturer for its Swoop® system. Additionally, the Company purchases raw materials from this manufacturer.

Segment Information

The Company's Chief Operating Decision Maker ("CODM") is its Chief Executive Officer ("CEO"). Legacy Hyperfine and Liminal represent two operating segments. Given the similar qualitative and economic characteristics of the two operating segments, such that both are focused upon the development and commercialization of existing and new products and services, Legacy Hyperfine and Liminal are aggregated into one reporting unit. All of the Company's long-lived assets are located in the United States. Other than $2,538 and $78 of revenue recognized in non-U.S. countries for the years ended December 31, 2022 and 2021, respectively, all of the revenues during these periods were earned in the United States. Since the Company is aggregated into a single reportable unit, all required financial segment information is provided in the combined and consolidated financial statements.

Use of Estimates

The preparation of the combined and consolidated financial statements in conformity with U.S. GAAP requires the Company to make estimates and assumptions about future events that affect the amounts reported in its combined and consolidated financial statements and accompanying notes. Future events and their effects cannot be determined with certainty. On an ongoing basis, management evaluates these estimates and assumptions. Significant estimates and assumptions included:

- Revenue recognition, including determination of the timing and pattern of satisfaction of performance obligations, determination of the standalone selling price ("SSP") of performance obligations and estimation of variable consideration if any;
- Allowance for doubtful accounts;
- Net realizable value (the selling price as well as estimated costs of disposal and transportation) of inventory, and demand and future use of inventory;
- Valuation allowances with respect to deferred tax assets; and
- Assumptions underlying the fair value used in calculation of the stock-based compensation expense.

The Company bases these estimates on historical and anticipated results and trends and on various other assumptions that the Company believes are reasonable under the circumstances, including assumptions as to future events. Changes in estimates are recorded in the period in which they become known. Actual results could differ from those estimates, and any such differences may be material to the Company's combined and consolidated financial statements.

Cash and Cash Equivalents

All highly liquid investments purchased with a maturity of three months or less are cash equivalents. As of December 31, 2022 and 2021, cash and cash equivalents consist principally of cash and money market accounts. The Company funded its operations primarily with proceeds from the issuance of common and preferred stock. The Company incurred significant cash burn and recurring net losses, which includes a net loss of $73,164 for the year ended December 31, 2022, and an accumulated deficit of $209,484 as of December 31, 2022. As of December 31, 2022, the Company had cash and cash equivalents of $117,472.

Restricted Cash

Restricted cash balance represents funds received as part of grant funding and restricted in use to the purpose of the funding. For details, see the Note 2. *Summary of Significant Accounting Policies - Grant Funding* and Note 14. *Commitments and Contingencies.*

Accounts Receivable

Accounts receivable are stated as the amount the Company expects to collect. The Company maintains allowance for doubtful accounts for estimated losses resulting from the inability of its customers to make required payments. As of December 31, 2022 and 2021, the allowance for doubtful accounts was $180 and $32, respectively.

Inventories

Inventories primarily consist of finished goods which are produced by the Company's third-party contract manufacturers as well as raw materials ordered in advance by the third-party contract manufacturer due to long delivery-lead time and which were billed to the Company. Inventories are stated at the lower of actual cost, determined using the average cost method, or net realizable value. Cost includes an allocation of wages, taxes and benefits for employees involved in warehousing, logistics coordination, material sourcing, and production planning activities. Net realizable value is based upon an estimated average selling price reduced by the estimated costs of disposal and transportation.

The valuation of inventory also requires the Company to estimate excess and obsolete inventory. The Company considers sales forecasts and historical experience to identify excess, close out, or slow-moving items as well as new product development schedules, product obsolescence and product merchantability, including whether older products can be remanufactured into new products, among other factors. The Company reduces the value of inventory for estimated obsolescence or lack of marketability by the difference between the cost of the affected inventory and the net realizable value.

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets include amounts paid in advance for operating expenses as well as monies to be received from the State of Connecticut for research and development tax credits. These research and development tax credits are exchanged for a cash refund and are typically collected within one year from the date the tax return is filed with the state. The credits are recognized as an offset to research and development expenses in the combined and consolidated statements of operations and comprehensive loss in the annual period in which the corresponding expenses were incurred.

(all amounts are in thousands, except share and per share data)

Property and Equipment, Net

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation expense is computed using the straight-line method over the estimated useful lives of the related assets. MRI devices purchased from a third-party manufacturer that were intended for use as research units, for customer demonstration purposes to support sales efforts and training and as leased units are classified as Property and Equipment.

Useful lives of property and equipment are as follows:

Property and equipment	Estimated useful life
Laboratory equipment	5
Research devices	5
Sales and marketing devices	5
Computer equipment	5
Tooling	3
Trade show assets	3
Leased devices	5
Other	3-7

Other property and equipment include furniture and fixtures, software, vehicles, and machinery and equipment.

Expenditures for major renewals and improvements are capitalized. Expenditures for repairs and maintenance are expensed as incurred. When assets are retired or otherwise disposed of, the cost of these assets and related accumulated depreciation is eliminated from the balance sheet, and any resulting gains or losses are included in the combined and consolidated statements of operations and comprehensive loss in the period of disposal.

Impairment of Long-Lived Assets

The Company reviews its long-lived assets for impairment at least annually or when the Company determines a triggering event has occurred. When a triggering event has occurred, each impairment test is based on a comparison of the future expected undiscounted cash flow to the recorded value of the asset. If the recorded value of the asset is less than the undiscounted cash flow, the asset is written down to its estimated fair value. Impairments were recorded for the years ended December 31, 2022 of $80 and no impairment recorded for the year ended December 31, 2021 (see Note 15. Restructuring).

Capitalized Software Development Costs

For the costs incurred in developing the firmware embedded in the hardware devices that the Company sells and leases to its customers, the Company applies the principles of Financial Accounting Standards Board (“FASB”) Accounting Standards Codification (“ASC”) 985-20, *Accounting for the Costs of Computer Software to Be Sold, Leased, or Otherwise Marketed* (“ASC 985-20”). ASC 985-20 requires that software development costs incurred in conjunction with product development be charged to research and development expense until technological feasibility is established. Thereafter, until the product is released for sale, software development costs must be capitalized and reported at the lower of unamortized cost or net realizable value of the related product. The Company has adopted the “tested working model” approach to establishing technological feasibility for its software products. Under this approach, the Company does not consider a product in development to have passed the technological feasibility milestone until the Company has completed a model of the product that contains essentially all the functionality and features of the final product and has tested the model to ensure that it works as expected. The Company’s hardware device, with the embedded firmware, was released for sale during the fourth quarter of the year ended December 31, 2020, when the Company had completed all of the research and development activity to establish the technological feasibility of the product. As of December 31, 2022 and 2021, the Company had not incurred significant costs between the establishment of technological feasibility and the release of a product for sale; thus, the Company had expensed all software development costs as incurred.

For software developed or acquired for internal use, including software used in the provision of subscription services to the Company's customers, the Company applies the principles of ASC 350-40, *Accounting for the Cost of Computer Software Developed or Obtained for Internal Use* ("ASC 350-40"). ASC 350-40 requires that software development costs incurred before the preliminary project stage be expensed as incurred. The Company capitalizes development costs related to these software applications once the preliminary project stage is complete and it is probable that the project will be completed, and the software will be used to perform the function intended. Costs incurred during the preliminary project and post-implementation stages, including training and maintenance, are expensed as incurred. Capitalized costs are amortized on a project-by-project basis using the straight-line method over the estimated economic life of the application, which is three years, beginning when the asset is substantially ready for use. As of December 31, 2022 and 2021, the Company did not have any amount of capitalized internal-use software development costs.

Revenue Recognition

The Company recognizes revenue in accordance with ASC Topic 606, "*Revenue from Contracts with Customers."*

Revenue is recognized when or as a customer obtains control of the promised goods and services. The amount of revenue recognized reflects the consideration to which the Company expects to be entitled in exchange for these goods and services. To achieve this core principle, the Company applies the following 5 steps:

• *Step 1: Identify Contracts with Customers:* The Company executes signed contracts with its customers for the sale of hardware devices and subscription services.

• *Step 2: Identify Performance Obligations:* The Company's contracts with customers primarily include two performance obligations, namely the hardware device and subscription services, which include access to the Company's hosted cloud-based software applications and hardware maintenance and support on an ongoing basis throughout the subscription period.

• *Step 3: Determine Transaction Price:* The Company's contracts with customers include variable consideration in the form of discounts and price concessions. The Company estimates variable consideration using the expected value method based on the data available as of the end of each reporting period.

• *Step 4: Allocate Transaction Price to Performance Obligations:* The Company allocates transaction price to the performance obligations in a contract with a customer, based on the relative standalone selling prices of the goods and services. The standalone selling prices of the hardware devices and subscription services are determined based on the observable standalone selling prices for which the Company sells the respective goods and services on a standalone basis, including renewals of subscription services.

• *Step 5: Recognize Revenue as Performance Obligations are Satisfied:* Each unit of hardware devices is a performance obligation satisfied at a point in time, when control of the good transfers from the Company to the customer, which is typically upon shipment of the good to the customer. For sales of hardware where control of the product transfers to the customer upon shipment, the Company has made an accounting policy election to account for shipping and handling as fulfillment activities rather than a performance obligation. The subscription services are stand-ready obligations that are satisfied over time by providing the customer with ongoing access to the Company's resources throughout the subscription period. The Company uses the time elapsed (straight-line) measure of progress to recognize revenue as these performance obligations are satisfied evenly over the respective service period.

The Company offers alternative payment structures and "as-a-service" offerings that are assessed to determine whether an embedded lease arrangement exists. The Company accounts for those contracts as a lease arrangement under ASC 842 and ASC 840, Leases for the years ended December 31, 2022 and 2021, respectively. The Company identify certain Device-as-a-Service contracts to be within the scope of ASC 842 and ASC 606. Revenue from contracts with customers upon adoption of ASC 842, in which the Company acts as a lessor. For contracts that are in the scope of both ASC 842 and ASC 606, and in which the lease component is an operating lease, the Company has applied the practical expedient in ASC 842 to combine the lease component (the device itself in device as a service,

("DaaS") contracts) and non-lease (maintenance and SaaS) components, and to account for the combined components as a single lease component. Accordingly, the Company accounts for the monthly payments as lease revenue. For contracts in which the lease component is a sales-type lease, the Company derecognizes the asset (the MRI device) and recognizes a lease receivable in an amount that represents the present value of the lease payments. At times, the Company may enter into arrangements with payment terms which exceed one year from the transfer of control of the product or service. In such cases, the Company assesses whether the arrangement contains a significant component. If a significant financing component exists, the transaction price is adjusted for the financing portion of the arrangement, which is recorded as interest income over the payment term using the effective interest method. The Company does not assess whether a significant component exists when, at contract inception, the period between the transfer of control to a customer and final payment is one year or less.

Deferred Revenue

Deferred revenue primarily consists of billings or payments received in advance of revenue recognition from subscription services described above and is reduced as the revenue recognition criteria are met. Deferred revenue is classified as current based on expected revenue recognition timing. Specifically, deferred revenue that will be recognized as revenue within the succeeding 12 month period is recorded as deferred revenue as part of current liabilities and the remaining portion is recorded as long term deferred revenue in the Company’s combined and consolidated balance sheets.

Warranties

The Company offers a device warranty to customers for the longer of (a) 12 months from delivery of the device for devices obtained through a capital purchase, or (b) the term of the subscription agreement for devices obtained on a subscription basis (subject to continued payment of fees for the subscription service). The Company’s subscription services include hardware maintenance and support. As noted in the accounting policy for revenue recognition, the Company recognizes revenue for subscription service over time using the time elapsed measure of progress. The costs of hardware maintenance are recognized in costs of revenue as they are incurred.

Research and Development

Research and development costs consists of production costs for prototype, test and pre-production units, lab supplies, consulting and personnel costs, including salaries, stock-based compensation, bonuses, benefit costs and depreciation. Certain research and development grant funding is recognized as a reduction to research and development costs (see Note 2. *Summary of Significant Accounting Policies - Grant Funding*). The Company recognizes these costs as they are incurred.

Grant Funding

The Company received certain research and development funding through a grant issued by the Bill & Melinda Gates Foundation (“BMGF”). Funding is recorded on the combined and consolidated balance sheet as restricted cash upon receipt. The funding is recognized in the combined and consolidated statements of operations and comprehensive loss as a reduction to research and development expense in the period when milestone deliverables are fulfilled and met. Grant funding payments received in advance of research and development expenses incurred are recorded as deferred grant funding as a current liability in the Company’s combined and consolidated balance sheets.

Cost of Sales

Cost of sales consists of product and service costs including personnel cost and benefits including stock-based compensation, product costs, production setup expenses, depreciation expenses, inventory excess and obsolescence expenses.

Patent Costs

Patent costs have been charged to operations as incurred, as their realization is uncertain. These costs are included in general and administrative expenses in the combined and consolidated statements of operations and comprehensive loss.

General and Administrative

General and administrative expenses primarily consist of personnel costs and benefits including stock-based compensation, patent and filing fees, office expenses and outside services. Outside services consist of professional services, legal and other professional fees.

Sales and Marketing

Sales and marketing costs primarily consist of personnel costs and benefits including stock-based compensation, advertising, promotional, as well as conferences, meetings, and other events. Advertising costs are expensed as incurred. For the years ended December 31, 2022 and 2021, advertising expenses were $1,338 and $2,459, respectively.

Net Loss per Common Share

Basic net loss per common share is calculated by dividing the net loss attributed to common stockholders by the weighted average number of common shares outstanding during the period, without consideration of potentially dilutive securities.

Diluted net loss per common share is computed by dividing the net loss attributable to common stockholders by the weighted average number of common shares plus the common equivalent shares of the period, including any dilutive effect from such shares. The Company's diluted net loss per common share is the same as basic net loss per common share for all periods presented since the effect of potentially dilutive securities is anti-dilutive.

Convertible Preferred Stock

The Company has applied the guidance in ASC Topic 480-10-S99-3A, *SEC Staff Announcement: Classification and Measurement of Redeemable Securities*, and has therefore classified the Series A, Series B, Series C and Series D Convertible Preferred Stock ("Convertible Preferred Stock") (see Note 10. *Convertible Preferred Stock*) as mezzanine equity. The Convertible Preferred Stock was recorded outside of stockholders' equity (deficit) because the Convertible Preferred Stock included a redemption provision upon a change of control, which is deemed a liquidation event that is considered outside the Company's control. The Convertible Preferred Stock has been recorded at its original issue price, net of issuance costs. The Company did not adjust the carrying value of the Convertible Preferred Stock to the liquidation price associated with a change of control at December 31, 2020 because a change of control of the Company was not considered probable at the reporting date (see Note 10. *Convertible Preferred Stock*). Subsequent adjustments to increase or decrease the carrying values to their respective liquidation prices were made only when it became probable that such a change of control would occur.

Stock-Based Compensation

The measurement of stock-based compensation expense for all stock-based payment awards, including stock options granted to employees, directors, and consultants, is based on the estimated fair value of the awards on the date of grant.

The Company recognizes stock-based compensation expense for stock option grants and incentive unit grants with only service conditions on a straight-line basis over the requisite service period of the individual grants, which is generally the vesting period, based on the estimated grant date fair values. Generally, stock option grants and incentive unit grants fully vest four years after the grant date, and stock option grants generally have a term of 10 years.

The Company recognizes the effect of forfeiture in compensation costs based on actual forfeitures when they occur.

The Company's stock-based compensation program includes stock option grants to its employees, directors, and consultants. Stock options are granted at exercise prices not less than the estimated fair market value of the Company's common stock at the date of grant.

The fair values of stock option grants are estimated using a Black-Scholes option-pricing model. Key inputs and assumptions include the expected term of the option, stock price volatility, risk free interest rate, dividend yield, stock price and exercise price. Many of the assumptions require significant judgment and any changes could have a material impact in the determination of stock-based compensation expense.

During the year ended December 31, 2020, Liminal was a wholly owned subsidiary of 4Bionics, and as such, 4Bionics granted equity awards in the form of incentive units to Liminal employees and nonemployees under 4Bionics' stock-based compensation program.

On April 2, 2021, 4Bionics executed a plan of liquidation and dissolution and its ownership in Liminal was distributed to its members and to the holders of incentive units. Immediately subsequent to the dissolution, all outstanding unvested incentive unit awards under 4Bionic's 2019 Equity Incentive Plan were replaced with preferred stock awards indexed to and settled in the preferred stock of the former 4Bionics subsidiaries Liminal, Detect, Inc. (f/k/a Homodeus Inc.), identifeye HEALTH Inc. (f/k/a Tesseract Health, Inc.) and Protein Evolution, Inc. The preferred stock awards were subject to service vesting conditions only. No incremental value was provided to participants as a result of the modification of the awards as the modification date fair value of the incentive unit awards was equal to the modification date fair value of the stock underlying the restricted stock awards. Moreover, the remaining vesting period before and after modification was unchanged.

Earn-Out Shares

Earn-Out Shares, as defined in Note 3. *Business Combination*, to which the Companies' pre-closing equity holders are entitled, fall within the scope of ASC 815, *Derivatives and Hedging* ("ASC 815") pursuant to which such Earn-Out Shares are equity classified and are to be recognized upon achievement of the market price milestone.

Earn-Out Shares to which certain employees are entitled to fall within the scope of ASC 718, Compensation – Stock Compensation ("ASC 718"), pursuant to which such Earn-Out Shares are equity classified and their grant date fair value will be recognized as compensation expense over the vesting period.

Research and Development Tax Credits

The Company recognizes research and development tax credits as a reduction of research and development expense as earned. For State of Connecticut research and development tax credits, which are exchanged for a cash refund from the State of Connecticut, such exchanged credits are recognized as earned as a reduction of research and development expense in the combined and consolidated statements of operations and comprehensive loss.

Income Taxes

The Company utilizes the asset and liability method of accounting for income taxes, as set forth in ASC Topic 740, *Income Taxes*. Under this method, deferred tax assets and liabilities are recognized for the expected future tax consequences of temporary differences between the carrying amounts and the tax basis of assets and liabilities using the enacted statutory tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. A valuation allowance is established against net deferred tax assets if, based on the weight of available evidence, it is more likely than not that some or all of the net deferred tax assets will not be realized. The Company has recorded a full valuation allowance as of December 31, 2022 and 2021. Based on the available evidence, the Company believes that it is more likely than not that it will be unable to utilize all of its deferred tax assets in the future.

In accordance with the provisions of ASC Topic 740, the Company accrues for the estimated amount of taxes for uncertain tax positions if it is more likely than not that the Company would be required to pay such additional taxes. An uncertain tax position will not be recognized if it has a less than 50% likelihood of being sustained. The Company's policy is to recognize any interest and penalties related to income taxes in income tax expense in the combined and consolidated statements of operations and comprehensive loss. The Company's open tax years subject to examination by the relevant taxing authorities are 2017 through 2019. As of December 31, 2022 and 2021, the Company had no uncertain tax positions.

Recent Accounting Pronouncements

Accounting pronouncements adopted

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842), which outlines a comprehensive lease accounting model and supersedes the current lease guidance. The new guidance requires lessees to recognize almost all of their leases on the balance sheet by recording a lease liability and corresponding right-of-use assets. It also changes the definition of a lease and expands the disclosure requirements of lease arrangements. As per the latest ASU 2020-05 issued by the FASB, entities that have not yet issued or made available for issuance the financial statements as of June 3, 2020 can defer the new guidance for one year. For public entities, this guidance is effective for annual reporting periods beginning January 1, 2020, including interim periods within that annual reporting period. For the Company, this guidance is effective for annual reporting periods beginning January 1, 2022, and interim reporting periods within annual reporting periods beginning January 1, 2023. The Company adopted this guidance including the election of the effective date modified retrospective transition approach, the package of practical expedients applied in the transition on January 1, 2022 and there was no material effect of adoption on the combined and consolidated financial statements.

As part of the adoption of Topic 842, the Company made the following practical expedient elections:

- We elected the package of practical expedients available for transition which allow us to not reassess whether expired or existing contracts contain leases under the new definition of a lease, lease classification for expired or existing leases and whether previously capitalized initial direct costs would qualify for capitalization under ASC 842.
- We did not elect to use hindsight when considering judgments and estimates such as assessments of lessee options to extend or terminate a lease or purchase the underlying asset.
- For all asset classes, we elected to not recognize a right-of-use asset and lease liability for short-term leases.
- For all asset classes, we elected to not separate non-lease components from lease components to which they relate and have accounted for the combined lease and non-lease components as a single lease component.

The Company identified certain Device-as-a-Service contracts to be within the scope of ASC 842 and ASC 606, Revenue from Contracts with Customers upon adoption of ASC 842, in which the Company acts as a lessor. For contracts that are in the scope of both ASC 842 and ASC 606, and in which the lease component is an operating lease, the Company has applied the practical expedient in ASC 842 to combine the lease component (the device itself in device as a service, ("DaaS") contracts) and non-lease (maintenance and SaaS) components, and to account for the combined components as a single lease component. Accordingly, the Company accounts for the monthly payments as lease revenue. For contracts in which the lease component is a sales-type lease, the Company derecognizes the asset (the MRI device) and recognizes a lease receivable in an amount that represents the present value of the lease payments.

Accounting pronouncements issued but not yet adopted

In June 2016, the FASB issued ASU No. 2016-13, *"Financial Instruments — Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments,"* which was subsequently amended in November 2018 through ASU No. 2018-19, *"Codification Improvements to Topic 326, Financial Instruments — Credit Losses."* ASU No. 2016-13 will require entities to estimate lifetime expected credit losses for trade and other receivables, net investments in leases, financing receivables, debt securities and other instruments, which will result in earlier recognition of credit losses. Further, the new credit loss model will affect how entities in all industries estimate their allowance for losses for receivables that are current with respect to their payment terms. ASU No. 2018-19 further clarifies that receivables arising from operating leases are not within the scope of Topic 326. Instead, impairment from receivables of operating leases should be accounted for in accordance with Topic 842, *Leases*. As per the latest ASU 2020-02, the FASB deferred the timelines for certain small public and private entities, thus the new guidance will be adopted by the Company for the annual reporting period beginning January 1, 2023, including interim periods within that annual reporting period. The standard will apply as a cumulative-effect adjustment to retained earnings as of the beginning of the first reporting period in which the guidance is adopted. The Company is in the process of evaluating the impact that the adoption of this pronouncement will have on the Company's combined and consolidated financial statements and disclosures.

3. BUSINESS COMBINATION

At the Closing, Legacy Hyperfine and Liminal merged with and into separate wholly owned subsidiaries of HealthCor and each became a wholly-owned subsidiary of the Company. The Business Combination is accounted for as a reverse recapitalization in accordance with U.S. GAAP primarily due to the fact that Legacy Hyperfine and Liminal stockholders continued to control the Company following the closing of the Business Combination. Under this method of accounting, HealthCor is treated as the "acquired" company for accounting purposes and the Business Combination is treated as the equivalent of Legacy Hyperfine and Liminal issuing stock for the net assets of HealthCor, accompanied by a recapitalization. The net assets of HealthCor are stated at historical cost, with no goodwill or other intangible assets recorded. Reported shares and loss per share available to holders of the Company's capital stock and equity awards prior to the Business Combination have been retroactively restated reflecting the exchange ratios established pursuant to the Business Combination Agreement dated as of July 7, 2021 (the "Business Combination Agreement").

Pursuant to the Business Combination Agreement, at the effective time of the Business Combination (the "Effective Time"):

- each share of Legacy Hyperfine capital stock (other than shares of Legacy Hyperfine Series A preferred stock) that was issued and outstanding as of immediately prior to the Effective Time was automatically cancelled and extinguished and converted into the right to receive a number of shares of the Company's Class A common stock equal to 0.3275 (the "Hyperfine Exchange Ratio"), rounded down to the nearest whole number of shares;

- each share of Legacy Hyperfine Series A preferred stock that was issued and outstanding as of immediately prior to the Effective Time was automatically cancelled and extinguished and converted into the right to receive a number of shares of the Company's Class B common stock equal to the Hyperfine Exchange Ratio, rounded down to the nearest whole number of shares;

- each share of Liminal capital stock (other than shares of Liminal Series A-1 preferred stock) that was issued and outstanding as of immediately prior to the Effective Time was automatically cancelled and extinguished and converted into the right to receive a number of shares of the Company's Class A common stock equal to 0.1796 (the "Liminal Exchange Ratio"), rounded down to the nearest whole number of shares;

- each share of Liminal Series A-1 preferred stock that was issued and outstanding as of immediately prior to the Effective Time was automatically cancelled and extinguished and converted into the right to receive a number of shares of the Company's Class B common stock equal to the Liminal Exchange Ratio, rounded down to the nearest whole number of shares;

• each option to purchase shares of Legacy Hyperfine common stock and each option to purchase shares of Liminal common stock, whether vested or unvested, that was outstanding and unexercised as of immediately prior to the Effective Time was assumed by the Company and became an option (vested or unvested, as applicable) to purchase a number of shares of the Company's Class A common stock equal to the number of shares of Legacy Hyperfine common stock or Liminal common stock subject to such option immediately prior to the Effective Time multiplied by the Hyperfine Exchange Ratio or the Liminal Exchange Ratio, as applicable, rounded down to the nearest whole number of shares, at an exercise price per share equal to the exercise price per share of such option immediately prior to the Effective Time divided by the Hyperfine Exchange Ratio or the Liminal Exchange Ratio, as applicable, rounded up to the nearest whole cent; and

• each Legacy Hyperfine restricted stock unit and each Liminal restricted stock unit outstanding immediately prior to the Effective Time was assumed by the Company and became a restricted stock unit with respect to a number of shares of the Company's Class A common stock equal to the number of shares of Legacy Hyperfine common stock or Liminal common stock subject to such Legacy Hyperfine restricted stock unit or Liminal restricted stock unit immediately prior to the Effective Time multiplied by the Hyperfine Exchange Ratio or the Liminal Exchange Ratio, as applicable, rounded down to the nearest whole share.

Pursuant to the Business Combination Agreement, the Company will issue to holders of Legacy Hyperfine and Liminal securities as of immediately prior to the Effective Time, in accordance with their pro rata share, up to 10,000,000 shares of Class A common stock as earn-out consideration (the "Earn-Out Shares"), if at any time during the period between the Closing Date and the third anniversary of the Closing Date (the "Earn-Out Period"), (i) the last share price of the Class A common stock is greater than or equal to $15.00 for any 20 trading days within any 30 consecutive trading day period, or (ii) there is a transaction that will result in shares of Class A common stock being converted or exchanged into the right to receive cash or other consideration having a value greater than or equal to $15.00. During the Earn-Out Period, if there is a transaction (other than for stock splits, stock dividends, special cash dividends, reorganizations, recapitalizations or similar transactions affecting the Class A common stock) that will result in the shares of Class A common stock being converted or exchanged into the right to receive cash or other consideration having a value less than $15.00, then the right to receive Earn-Out Shares will terminate.

On December 21, 2021, HealthCor filed the Certificate of Incorporation (the "Certificate") with the Secretary of State of the State of Delaware, which became effective after the Domestication. As a consequence of filing the Certificate, the Company adopted a dual class structure, comprised of the Company's Class A common stock, which is entitled to one vote per share, and the Company's Class B common stock, which is entitled to 20 votes per share. The Company's Class B common stock has the same economic terms as the Company's Class A common stock, but is subject to a "sunset" provision if Jonathan M. Rothberg, Ph.D., the founder of Legacy Hyperfine and Liminal, and a Director of the Company ("Dr. Rothberg"), and other permitted holders of the Company's Class B common stock collectively cease to beneficially own at least twenty percent (20%) of the number of shares of the Company's Class B common stock (as such number of shares is equitably adjusted in respect of any reclassification, stock dividend, subdivision, combination or recapitalization of the Company's Class B common stock) collectively held by Dr. Rothberg and permitted transferees of the Company's Class B common stock as of the Effective Time. At the Effective Time, the Company amended the Certificate to change the name of the Company from HealthCor Catalio Acquisition Corp. to "Hyperfine, Inc." (the Certificate, as amended, the "Amended Certificate").

Concurrently with the execution of the Business Combination Agreement, HealthCor entered into subscription agreements (the "Subscription Agreements") with certain institutional investors and accredited investors (the "PIPE Investors"), pursuant to which the PIPE Investors purchased, immediately prior to the Closing, an aggregate of 12,610,000 shares of HealthCor Class A common stock at a purchase price of $10.00 per share (the "PIPE Investment").

Additionally, on December 22, 2021, HealthCor, HC Sponsor LLC (the "Sponsor"), Legacy Hyperfine and Liminal entered into a Forfeiture Agreement (the "Forfeiture Agreement"), pursuant to which, immediately prior to the Closing, 150,000 shares of HealthCor's Class B common stock held by the Sponsor were irrevocably forfeited and automatically cancelled (the "Forfeiture").

(all amounts are in thousands, except share and per share data)

The total number of shares of the Company's Class A common stock outstanding immediately following the Closing was 54,977,061 comprising:

- 29,711,224 shares of Class A common stock issued to Hyperfine stockholders (other than certain holders of Hyperfine Series A preferred stock);

- 3,459,081 shares of Class A common stock issued to Liminal stockholders (other than certain holders of Liminal Series A-1 preferred stock);

- 12,610,000 shares of Class A common stock issued in connection with the Closing to the PIPE Investors pursuant to the PIPE Investment;

- 5,025,000 shares of Class A common stock issued immediately prior to the Effective Time to the initial shareholders upon conversion of the 5,025,000 shares of Class B common stock outstanding immediately prior to the Effective Time (following the issuance of the 5,175,000 shares of Class B common stock upon the Conversion of the 5,175,000 Class B ordinary shares held by the initial shareholders and after reflecting the irrevocable forfeiture by the Sponsor to HealthCor of 150,000 shares of Class B common stock for no consideration and automatic cancellation as of immediately prior to the Closing);

- 614,000 shares of Class A common stock issued to the Sponsor; and

- 3,557,756 shares of Class A common stock issued to the Company's public stockholders holding 3,557,756 Class A ordinary shares outstanding at the Effective Time, after reflecting redemptions of 17,142,244 shares of HealthCor Class A common stock.

The total number of shares of the Company's Class B common stock outstanding immediately following the Closing was 15,055,288 shares. Immediately following the Closing, Dr. Rothberg held approximately 84.8% of the combined voting power of the Company. Accordingly, Dr. Rothberg and his permitted transferees control the Company, and the Company is a controlled company within the meaning of the Nasdaq listing rules.

Net equity infusion from the Business Combination was $141,471, which consists of $207,448 proceeds from HealthCor, $126,100 proceeds from the PIPE Investors, net of payments to redeeming HealthCor shareholders of $171,437 and payment of transaction costs of $20,640. Additionally, 300,000 shares of Class A Common Stock were issued in connection with the Business Combination to a service provider in exchange for the services provided in connection with HealthCor's initial public offering.

In December 2021, in connection with the closing of the Business Combination, the Company prepaid directors and officers insurance policy in the amount of $1,244 and repaid the Liminal Paycheck Protection Program ("PPP") loan in full in the amount of $113.

4. REVENUE RECOGNITION

Disaggregation of Revenue

The Company disaggregates revenue from contracts with customers by product type. The Company believes that these categories aggregate the payor types by nature, amount, timing and uncertainty of its revenue streams. The following table summarizes the Company's disaggregated revenues:

	Pattern of Recognition	2022	2021
Device	Point in time	$ 5,246	$ 715
Service	Over time	1,568	781
Total revenue		**$ 6,814**	**$ 1,496**

(all amounts are in thousands, except share and per share data)

Contract Balances

Contract balances represent amounts presented in the combined and consolidated balance sheets when either the Company has transferred goods or services to the customer, or the customer has paid consideration to the Company under the contract. These contract balances include trade accounts receivable and deferred revenue. Deferred revenue represents consideration received from customers at the beginning of the subscription period for services that are transferred to the customer over the respective subscription period. The accounts receivable balances represent amounts billed to customers for goods and services where the Company has an unconditional right to payment of the amount billed.

The following table provides information about receivables and deferred revenue from contracts with customers:

	2022	2021
Accounts receivable	$ 2,103	$ 553
Unbilled receivables - current	454	91
Unbilled receivables - non-current [(1)]	744	—
Deferred revenue	1,378	730
Long term deferred revenue	1,526	510

(1) Recorded in other long term assets in the Company's combined and consolidated balance sheets.

The Company recognizes a receivable when it has an unconditional right to payment, and payment terms range from 30 days to less than one year based on the terms agreed upon with the respective customer.

Accounts Receivable, Unbilled Services, and Deferred Revenue

Accounts receivable are recorded at net realizable value. Unbilled receivable arise when performance obligations are satisfied for which revenue has been recognized but the customers have not been billed. Contractual provisions and payment schedules may or may not correspond to the timing of the performance of services under the contract.

Deferred revenue is a contact liability that consists of customer payments received in advance of performance and billings in excess of revenue recognized, net of revenue recognized from the balance at the beginning of the period.

The amount of revenue recognized during the years ended December 31, 2022 and 2021 that was included in the deferred revenue balance at the beginning of the period was $593 and $158, respectively.

Timing of Billing and Performance

Difference in the timing of revenue recognition and associated billings and cash collections result in recording of billed accounts receivable, unbilled accounts receivable (including contract assets), and deferred revenue on the combined consolidated balance sheet. Amounts are billed in accordance with the agreed-upon contractual terms, resulting in recording unbilled accounts receivable in instances where the right to bill is contingent solely on the passage of time, and contract assets in instances where the right to consideration is conditional on something other than the passage of time.

Revenue from Leasing Arrangements

Revenue from leasing arrangements is not subject to the revenue standard for contracts with customers and remains separately accounted for under ASC 842 and ASC 840, Leases for the years ended December 31, 2022 and 2021. The Company records operating lease rental revenue as service revenue on a straight-line basis over the lease term. The Company records revenue from the sale of hardware devices under sales-type leases as device revenue in an amount equal to the present value of minimum lease payments at the inception of the lease. Sales-type leases also produce financing income, which is included in device revenue in the combined and consolidated statements of operations and comprehensive loss and is recognized at effective rates of return over the lease term.

Costs of Obtaining or Fulfilling Contracts

The Company incurs incremental costs of obtaining contracts with customers. Incremental costs of obtaining contracts, which include commissions paid as a result of obtaining contracts with customers, are capitalized to the extent that the Company expects to recover such costs. Capitalized costs are amortized in a pattern that is consistent with the Company's transfer to the customer of the related goods and services. Such costs are recorded in Other long term assets and were $247 and $158 as of December 31, 2022 and 2021, respectively. During the years ended December 31, 2022 and 2021 the Company recognized $331 and $29, respectively, in expense related to the amortization of the capitalized contract costs.

Transaction price allocated to remaining performance obligations

As of December 31, 2022 and 2021, the Company had remaining performance obligations amounting to $8,663 and $2,800, respectively. The Company expects to recognize approximately 62% of its remaining performance obligations as revenue in fiscal year 2023, and an additional 38% in fiscal year 2024 and thereafter.

Significant Judgements

The Company makes significant judgments applying the guidance related to the determination of the timing and pattern of satisfaction of performance obligations, determination of the standalone selling price of performance obligations and estimation of variable consideration if any.

Practical Expedients and Accounting Policy Elections

As a practical expedient, the Company does not adjust transaction price for the effects of a significant financing component in contracts in which the period between when the Company transfers the promised good or service to the customer and when the customer pays for that good or service is one year or less.

The Company has made an accounting policy election to exclude all sales taxes from the transaction price of its contracts with customers. Accordingly, sales taxes collected from customers and remitted to government authorities is not included in revenue and is accounted for as a liability until it has been remitted to the respective government authority.

5. FAIR VALUE OF FINANCIAL INSTRUMENTS

Fair value estimates of financial instruments are made at a specific point in time, based on relevant information about financial markets and specific financial instruments. As these estimates are subjective in nature, involving uncertainties and matters of significant judgment, they cannot be determined with precision. Changes in assumptions can significantly affect estimated fair value.

The Company measures fair value as the price that would be received to sell an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the reporting date. The Company utilizes a three-tier hierarchy, which prioritizes the inputs used in the valuation methodologies in measuring fair value:

Level 1 — Valuations based on quoted prices in active markets for identical assets or liabilities that an entity has the ability to access.

Level 2 — Valuations based on quoted prices for similar assets or liabilities, quoted prices for identical assets or liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable data for substantially the full term of the assets or liabilities.

Level 3 — Valuations based on inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. The Company has no assets or liabilities valued with Level 3 inputs.

(all amounts are in thousands, except share and per share data)

The carrying value of cash and cash equivalents, accounts payable and accrued expenses and other current liabilities approximates their fair values due to the short-term or on demand nature of these instruments.

There were no transfers between fair value measurement levels during the years ended December 31, 2022 and 2021.

The Company had $93,502 and $48,625 of money market funds and demand deposit accounts included in cash and cash equivalents and restricted cash as of December 31, 2022 and 2021, respectively. These assets were valued using quoted prices in active markets and accordingly were classified as Level 1.

6. INVENTORIES

A summary of inventories are as follows at December 31:

	2022	2021
Raw materials	$ 2,241	$ 2,355
Finished goods	2,381	1,955
Total inventories	**$ 4,622**	**$ 4,310**

Manufacturing overhead costs primarily include management's best estimate and allocation of the labor costs incurred related to acquiring finished goods from the Company's contract manufacturer. Labor costs include wages, taxes and benefits for employees involved in warehousing, logistics coordination, material sourcing, and production planning activities. The majority of these costs have been written off based on the Company's analysis of net realizable value.

7. PROPERTY AND EQUIPMENT, NET

Property and equipment, net, are recorded at historical cost and consist of the following at December 31:

	2022	2021
Laboratory equipment	$ 923	$ 989
Research devices	1,709	1,422
Sales and marketing devices	524	669
Computer equipment	623	575
Construction in progress	359	341
Tooling	372	302
Trade show assets	254	293
Leased devices	453	396
Other	353	176
	5,570	5,163
Less: Accumulated depreciation and amortization	(2,322)	(1,410)
Property and equipment, net	**$ 3,248**	**$ 3,753**

Depreciation expense amounted to $1,015 and $726 for the years ended December 31, 2022 and 2021, respectively.

(all amounts are in thousands, except share and per share data)

8. ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

Accrued expenses and other current liabilities consist of the following at December 31:

	2022	2021
Bonus	$ 2,674	$ 3,421
Contracted services	1,127	2,711
SPAC bonus and other costs	—	1,071
Legal fees	261	452
Payroll and related benefits	1,876	441
Other	38	19
Total accrued expenses and other current liabilities	**$ 5,976**	**$ 8,115**

9. CONVERTIBLE PREFERRED STOCK

Legacy Hyperfine Convertible Preferred Stock

Legacy Hyperfine had issued four series of Convertible Preferred Stock, Series A through Series D. The following table summarizes the authorized, issued and outstanding Convertible Preferred Stock of Legacy Hyperfine immediately prior to the Business Combination:

Class	Year of Class Issuance	Issuance Price per share	Shares Authorized	Shares Issued and Outstanding	Total Proceeds or Exchange Value	Issuance Costs	Net Carrying Value	Initial Liquidation Price per share
Series A	2014	$ 0.04	25,000,000	25,000,000	$ 1,000	$ 2	$ 998	$ 0.80
Series B	2017	0.80	10,625,000	10,625,000	8,500	—	8,500	0.80
Series C	2017	1.88	31,586,210	31,586,210	59,382	234	59,148	1.88
Series D	2020-2021	2.15	62,577,618	41,970,981	90,237	136	90,101	2.15
			129,788,828	**109,182,191**	**$ 159,119**	**$ 372**	**$ 158,747**	

The powers, preferences, rights, qualifications, limitations and restrictions of the shares of Convertible Preferred Stock were as follows:

Dividends

Dividends shall accrue to holders of the Convertible Preferred Stock at the rate of 8% of the original issue price for the applicable series of Convertible Preferred Stock, per annum subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization, reclassification and other similar events payable only when, and if, declared by Legacy Hyperfine's board of directors. The right to receive dividends on Convertible Preferred Stock is not cumulative, and therefore, if not declared in any year, the right to such dividends shall terminate and shall not carry forward into the next year. There have been no dividends declared to date.

Liquidation Rights

In the event of any liquidation, dissolution or winding up of Legacy Hyperfine, whether voluntary or involuntary or a deemed liquidation event (which includes a merger, the sale of all of Legacy Hyperfine's assets, or a transaction which the holders of capital stock of Legacy Hyperfine hold less than 50% of the voting securities) (each a "Liquidation Event"), the holders of the Convertible Preferred Stock are entitled to be paid out of the assets of Legacy Hyperfine available for distribution to stockholders, pari passu, at a liquidation price per share equal to the greater of: (1) the applicable original issue price of such Convertible Preferred Stock, plus any declared and unpaid dividends or (2) an amount that would have been payable had all the shares of the Convertible Preferred Stock been converted into Legacy Hyperfine common stock. These payments will be made to or set aside prior to the holders of shares of any other class or series of capital stock that is not, by its terms, senior to the Convertible Preferred Stock.

Voting Rights

The holders of shares of the Convertible Preferred Stock shall be entitled to vote on all matters on which the holders of shares of Legacy Hyperfine common stock shall be entitled to vote.

Each holder of record of shares of Series A Convertible Preferred Stock shall be entitled to ten votes per share of Legacy Hyperfine Special-voting common stock into which such Series A Convertible Preferred Stock are convertible, as discussed below under "Conversion," on all matters to be voted on by Legacy Hyperfine's stockholders. Each holder of record of shares of Series B Convertible Preferred Stock, Series C Convertible Preferred Stock and Series D Convertible Preferred Stock shall be entitled to one vote per share of Legacy Hyperfine common stock into which such Series B Convertible Preferred Stock, Series C Convertible Preferred Stock, and Series D Convertible Preferred Stock are convertible, as discussed below under Conversion, on all matters to be voted on by Legacy Hyperfine's stockholders. The holders of Convertible Preferred Stock and the holders of Legacy Hyperfine common stock shall vote together and not as separate classes. There shall be no series voting.

Conversion

Each share of Series A Convertible Preferred Stock is convertible, at the option of the holder, at any time after the date of issuance of such share, into shares of Legacy Hyperfine Special-voting common stock on a 1 to 1 conversion rate subject to customary anti-dilution adjustments and upon the issuance of additional shares of common stock for no consideration or consideration less than the conversion price of the Series A Convertible Preferred Stock. Each share of Series B Convertible Preferred Stock, Series C Convertible Preferred Stock and Series D Convertible Preferred Stock shall be convertible, at the option of the holder, at any time after the date of issuance into shares of Legacy Hyperfine common stock on a 1 to 1 conversion rate subject to customary anti-dilution adjustments and upon the issuance of additional shares of common stock for no consideration or consideration less than the conversion price of the respective series of Convertible Preferred Stock, which is equal to the original issuance price for each series of Convertible Preferred Stock.

Upon the earlier to occur of (i) election of the Convertible Preferred Stock by (A) the consent or vote of the majority holders of the Convertible Preferred Stock (voting together as a single class and not as separate series, and on an as-converted basis), (B) the consent or vote of the majority holders of Series C Convertible Preferred Stock (voting separately as a single class) and (C) the consent or vote of the majority holders of Series D Convertible Preferred Stock (voting separately as a single class) or (ii) the closing of a firm commitment underwritten initial public offering pursuant to an effective registration statement filed under the Securities Act of 1933 covering the offer and sale of shares of Legacy Hyperfine common stock in which the aggregate gross proceeds to Legacy Hyperfine are at least $80,000 (1) each share of Series A Convertible Preferred Stock shall automatically be converted into shares of Legacy Hyperfine Special-voting common stock on a 1 for 1 basis and (2) each share of Series B, Series C and Series D Convertible Preferred Stock shall automatically be converted into Legacy Hyperfine common stock on a 1 for 1 basis.

Upon the closing of the Business Combination, the Convertible Preferred Stock converted into Class A and Class B common stock based on the Business Combination's Hyperfine Exchange Ratio of 0.3275 of the Company's shares for each Legacy Hyperfine share. The Company recorded the conversion at the carrying value of the Convertible Preferred Stock at the time of the Closing. There are no shares of Convertible Preferred Stock outstanding as of December 31, 2021 and 2022.

Liminal Convertible Preferred Stock

On April 1, 2021 Liminal effected a recapitalization whereby each share of Liminal common stock outstanding was exchanged for shares of Liminal Series A-1 preferred stock and Liminal Series A-2 preferred stock. The value ascribed to the preferred stock is equivalent to the total amount of historical equity investments contributed by the common shareholder. There were no new investments or changes in control in conjunction with the recapitalization.

The powers, preferences, rights, qualifications, limitations and restrictions of the shares of Liminal Convertible Preferred Stock are as follows:

Dividends

Dividends shall accrue to holders of the Convertible Preferred Stock at the rate of 8% of the original issue price for the applicable series of Convertible Preferred Stock, per annum subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization, reclassification and other similar events payable only when, and if, declared by Liminal's board of directors. The right to receive dividends on Convertible Preferred Stock is not cumulative, and therefore, if not declared in any year, the right to such dividends shall terminate and shall not carry forward into the next year. There have been no dividends declared to date.

Liquidation Rights

In the event of any liquidation, dissolution or winding up of Liminal, whether voluntary or involuntary or a deemed liquidation event (which includes a merger, the sale of all of Liminal's assets, or a transaction which the holders of capital stock of Liminal hold less than 50% of the voting securities) (each a "Liquidation Event"), the holders of the Convertible Preferred Stock are entitled to be paid out of the assets of Liminal available for distribution to stockholders, pari passu, at a liquidation price per share equal to the greater of: (1) the applicable original issuance price of $.1287 per share for Series A-1 and Series A-2 Convertible Preferred Stock, plus any declared and unpaid dividends or (2) an amount that would have been payable had all the shares of the Convertible Preferred Stock been converted into Liminal common stock. These payments will be made to or set aside prior to the holders of shares of any other class or series of capital stock that is not, by its terms, senior to the Convertible Preferred Stock.

Voting Rights

The holders of shares of the Convertible Preferred Stock shall be entitled to vote on all matters on which the holders of shares of Liminal common stock shall be entitled to vote.

Each holder of record of shares of Series A-1 Convertible Preferred Stock shall be entitled to ten votes per share of Liminal Special-voting common stock into which such Series A-1 Convertible Preferred Stock are convertible, as discussed below under "Conversion," on all matters to be voted on by Liminal's stockholders. Each holder of record of shares of Series A-2 Convertible Preferred Stock shall be entitled to one vote per share of Liminal common stock into which such Series A-2 Convertible Preferred Stock are convertible, as discussed below under Conversion, on all matters to be voted on by Liminal's stockholders. The holders of Convertible Preferred Stock and the holders of Liminal common stock shall vote together and not as separate classes. There shall be no series voting.

Conversion

Each share of Series A-1 Convertible Preferred Stock is convertible, at the option of the holder, at any time after the date of issuance of such share, into shares of Liminal Special-voting common stock on a 1 to 1 conversion rate subject to customary anti-dilution adjustments and upon the issuance of additional shares of Liminal common stock for no consideration or consideration less than the conversion price of the Series A Convertible Preferred Stock. Each share of Series A-2 Convertible Preferred Stock shall be convertible, at the option of the holder, at any time after the date of issuance into shares of Liminal common stock on a 1 to 1 conversion rate subject to customary anti-dilution adjustments and upon the issuance of additional shares of common stock for no consideration or consideration less than the conversion price of the respective series of Convertible Preferred Stock, which is equal to the original issuance price for each series of Convertible Preferred Stock.

Upon the earlier to occur of (i) election of the Convertible Preferred Stock by the consent or vote of the majority holders of the Convertible Preferred Stock (voting together as a single class and not as separate series, and on an as-converted basis) or (ii) the closing of a firm commitment underwritten initial public offering pursuant to an effective registration statement filed under the Securities Act of 1933, as amended, covering the offer and sale of shares of Liminal common stock in which the aggregate gross proceeds to Liminal are at least $80,000 (1) each share of Series A-1 Convertible Preferred Stock shall automatically be converted into shares of Liminal Special-voting common stock on a 1 for 1 basis and (2) each share of Series A-2 Convertible Preferred Stock shall automatically be converted into Liminal common stock on a 1 for 1 basis.

Upon the closing of the Business Combination, the Liminal Convertible Preferred Stock converted into Class A and Class B common stock based on the Business Combination's Liminal Exchange Ratio of 0.1796 of the Company's shares for each Liminal share. The Company recorded the conversion at the carrying value of the Convertible Preferred Stock at the time of the Closing. There are no shares of Convertible Preferred Stock outstanding as of December 31, 2021.

10. EQUITY INCENTIVE PLAN

Hyperfine Inc. 2021 Equity Incentive Plan

A total of 16,013,762 shares of common stock are reserved for issuance under the Company's 2021 Equity Incentive Plan (the "Hyperfine Plan"). The Hyperfine Plan is administered by the Company's board of directors. The board of directors may grant restricted stock and options to purchase shares either as incentive stock options or non-qualified stock options. The option grants are subject to certain terms and conditions, option periods and conditions, exercise rights and privileges as set forth in the Hyperfine Plan. During the year ended December 31, 2022, the number of shares available for grant increased by 2,813,293 shares pursuant to the evergreen provision in the Hyperfine Plan that provides for an automatic annual increase in the number of shares available for grant under the Hyperfine Plan equal to the lesser of (i) 4% of the number of outstanding shares of common stock outstanding on the first day of the fiscal year, and (ii) an amount determined by the administrator of the Hyperfine Plan, beginning in fiscal year 2022 and ending on the second day of fiscal year 2031. At December 31, 2022, 6,522,133 shares of common stock remain available for issuance under the Hyperfine Plan.

Prior to the Business Combination, Legacy Hyperfine and Liminal were distinct entities with separate equity incentive plans for their employees and nonemployees. Both plans were subsequently adopted and assumed by the Company as a consequence of the Business Combination.

Stock option activity

Each stock option grant carries varying vesting schedules whereby the options become exercisable at the participant's sole discretion provided they are an employee, director or consultant of the Company on the applicable vesting date. Each option shall terminate not more than ten years from the date of the grant.

During the fourth quarter of 2022, the Company granted certain equity awards to the newly hired Chief Executive Officer. These awards include an option award to purchase 3,175,000 shares of Class A common stock which will vest based on continued service over a four year period.

During the quarter ended December 31, 2022, the Company initiated and carried out certain restructuring actions in order to reduce costs, including termination of employees. As part of the employees' severance, for certain employees the Company accelerated the vesting of unvested awards including 90,003 option awards and 33,281 of restricted stock unit awards and extended the exercise period for 346,028 vested options post-termination, which were treated as the modification of awards in connection with the termination of employees and resulted in an additional stock-based compensation expense of $143 representing the incremental fair value of the modified awards.

During the years ended December 31, 2022 and 2021, the Company granted certain equity awards to the Chief Executive Officer hired during 2021. These awards include (1) an option award to purchase 1,899,500 shares of Class A common stock which will vest based on continued service over a four year period, and (2) two separate option

(all amounts are in thousands, except share and per share data)

awards to purchase 474,875 shares of Class A common stock (949,750 options total), which will be fully vested upon the occurrence of various service, performance, and market conditions. The following awards were granted to the Chief Executive Officer during the year ended December 31, 2022: (1) 474,875 share option award which will vest based on continued service over a five year period, (2) a 300,000 share option award which will vest based on continued service over a four year period, (3) a restricted stock unit (RSU) award for 150,000 shares which will vest based on continued service over a four year period, and (4) an RSU award granted on April 26, 2022 for 649,350 shares which will vest in four installments from February 2023 through November 2023. On July 29, 2022, the former Chief Executive Officer's employment with the Company terminated; the 649,350 RSUs awarded on April 26, 2022 continue to remain outstanding until paid in accordance with the schedule set forth in the grant notice agreement.

Certain equity awards were also granted to the Executive Chairperson of the Legacy Hyperfine board of directors. The equity compensation included (1) an option award to purchase 712,312 shares of Class A common stock which will vest based on continued service, over four years and (2) two separate option awards to purchase 237,437 shares each of Class A common stock (474,874 shares in total), which will be fully vested upon the occurrence of various certain service, performance, and market conditions.

The service condition for these awards is satisfied by providing service to the Company based on the defined service period per the award agreement. The performance-based condition is satisfied upon the occurrence of a special purpose acquisition company ("SPAC") transaction, initial public offering ("IPO"), or financing event as defined in the award agreement. The market condition is satisfied by achieving various multiples of a defined price per share. The achievement of the performance condition and the commencement of the related expense recognition event cannot occur until the event is deemed probable, which only occurs once a SPAC transaction, IPO, or financing event has occurred. The performance condition was satisfied as a result of the Business Combination and the Company recognized a credit to stock-based compensation expense of $904 and an expense of $1,772 in connection with these awards during the year ended December 31, 2022 and 2021. None of the market conditions have been satisfied and as such, none of the awards are exercisable as of December 31, 2022 and 2021.

During the year ended December 31, 2021, the Company also granted 258,833 option awards subject to certain service and performance conditions. The service condition required the participant's continued employment with the Company through the applicable vesting date, and the performance condition required the consummation of a Sale, IPO, or SPAC transaction as defined in the option award agreement. These awards were forfeited and cancelled prior to the consummation of the Business Combination. As a Sale, IPO, or SPAC transaction did not occur prior to forfeiture, the Company did not record any stock-based compensation expense related to these option awards.

All options granted by the Company during the years ended December 31, 2022 and 2021 were granted with exercise prices equal to the estimated fair value of the Company's common stock at the date of grant, as determined by the Company's board of directors.

A summary of the stock option activity under the Hyperfine Plan is presented in the table below:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at January 1, 2021	1,903,479	$ 0.87	7.07	$ 2,073
Granted	6,771,237	3.37		
Exercised	(565,533)	2.65		
Forfeited	(587,047)	3.86		
Outstanding at December 31, 2021	7,522,136	$ 3.21	8.79	$ 30,052
Granted	8,685,663	2.43		
Exercised	(25,870)	0.26		
Forfeited / Expired	(5,462,365)	3.03		
Outstanding at December 31, 2022	10,719,564	$ 1.34		
Options exercisable at December 31, 2022	3,442,085	$ 1.97	8.71	$ 124
Vested and expected to vest at December 31, 2022	10,719,564	$ 1.34	8.75	$ 157

The Company received cash proceeds from the exercise of stock options of $7 and $1,497 during the years ended December 31, 2022 and 2021, respectively.

The total intrinsic value (the amount by which the stock price exceeds the exercise price of the option on the date of exercise) of the stock options exercised during the years ended December 31, 2022 and 2021, was $47 and $2,752, respectively. The weighted-average grant date fair value of options granted during the year ended December 31, 2022 and 2021 was $0.62 and $0.66, respectively.

During the years ended December 31, 2022 and 2021, the Company recognized $3,483 and $6,604, respectively, of share-based compensation expense for stock options granted to employees.

Tax benefits from tax deductions for exercised options and disqualifying dispositions in excess of the deferred tax asset attributable to stock compensation costs for such options are credited to additional paid-in capital. The benefits are recognized against income taxes. Realized excess tax benefits related to stock options exercises was zero for each of the years ended December 31, 2022 and 2021.

As of December 31, 2022, there was approximately $7,357 of unrecognized compensation cost, related to unvested stock options, which is expected to be recognized over a weighted average period of 2.89 years.

Stock Option Repricing

On September 26, 2022, stockholders controlled by Jonathan M. Rothberg, Ph.D., Vice Chairperson of the Company, representing a majority in voting power with respect to the Company's Class A common stock and the Company's Class B common stock, approved a one-time stock option repricing (the "Option Repricing"). The Board of Directors of the Company previously approved the Option Repricing on August 24, 2022, contingent upon stockholder approval of the Option Repricing. Stock options held by Dr. Rothberg were not repriced in the Option Repricing. The Option Repricing was effected on October 31, 2022. Unexercised options held by current employees and certain non-employee directors with exercise prices ranging from $1.28 to $5.24 per share were repriced on a one-for-one basis to $0.91 per share which represented the per share fair value of our Class A common stock as of the date of the repricing. There was no other modification to the vesting schedule of the previously issued options. As a result, 5,378,308 outstanding options, including 4,903,434 awards with service conditions and 474,874 awards with market and performance-based conditions, originally granted to purchase Class A common stock at prices ranging from $1.28 to $5.24 per share were repriced under this program.

The Company treated the repricing as a modification of the original awards and calculated additional compensation costs for the difference between the fair value of the modified award and the fair value of the original award on the modification date. The repricing of the awards with service conditions resulted in incremental stock-based compensation expense of $1,460. Expense of $456 related to vested shares was expensed on the repricing date and expense related to unvested shares is being amortized over the remaining vesting period of such stock options.

The repricing of the awards with market and performance-based conditions resulted in incremental stock-based compensation expense of $1, which is being amortized over the remaining requisite service period.

Stock option valuation inputs

The Company utilized the Black-Scholes option pricing model for determining the estimated fair value for service awards. The Black-Scholes model requires the use of subjective assumptions which determine the fair value of stock-based awards. The assumptions used to value option grants to employees and nonemployees for the years ended December 31, 2022 and 2021 were as follows:

(all amounts are in thousands, except share and per share data)

	2022	2021
Risk Free interest rate	0.91% - 4.18%	0.95% - 1.13%
Expected dividend yield	0%	0%
Expected term [(1)]	0.51 years - 7.50 years	5.40 years - 6.17 years
Expected volatility	49% - 56%	70%

(1) Expected term of 0.51 years related to certain employee award granted and forfeited within approximately six months.

Risk free interest rate

The risk free interest rate for periods within the expected term of the awards is based on the U.S. Treasury yield curve in effect at the time of the grant.

Expected dividend yield

The Company has never declared or paid any cash dividends and does not expect to pay any cash dividends in the foreseeable future.

Expected term

For employee awards, the Company calculates the expected term using the “simplified” method, which is the simple average of the vesting period and the contractual term. The simplified method is applied as the Company does not have sufficient historical data to provide a reasonable basis for an estimate of the expected term. The Company calculates expected term for employee awards that take into account the effects of employee’s expected exercise and post-vesting employment termination behavior.

Expected volatility

During the year ended December 31, 2022, the expected volatility was determined using the historical volatilities of several publicly listed peer companies over a period equivalent to the expected term of the awards.

During the year ended December 31, 2021, as Legacy Hyperfine was privately held from inception through the Closing and all option grants during 2021 occurred prior to the Closing Date, there was no specific historical or implied volatility information available. Accordingly, the Company estimates the expected volatility on the historical stock volatility of a group of similar companies that are publicly traded over a period equivalent to the expected term of the stock-based awards. Point estimates of expected annual equity volatility of 70% for December 31, 2021, were selected in the guideline companies’ historical range.

Exercise price

The exercise price is taken directly from the grant notice issued to employees and nonemployees.

The stock options granted to the Company's employees and nonemployees for the periods presented were as follows:

	2022	2021
Stock options granted to employee	7,901,501	3,534,844
Stock options granted to nonemployee	784,162	3,236,393
Total stock options granted	**8,685,663**	**6,771,237**

(all amounts are in thousands, except share and per share data)

Incentive Unit and Preferred Stock Award Activity

Incentive unit grants typically vest over a four year period provided the holder is an employee, director or consultant of the Company on the applicable vesting date. Upon termination of service, pursuant to the terms of the grant, the participant 1) immediately forfeits any unvested (but issued) incentive units and 2) the Company has the right, but not the obligation, to repurchase at the fair market value on the date of termination, any vested incentive units. The repurchase right is valid for 18 months commencing with the date of service.

On April 2, 2021, 4Bionics executed a plan of liquidation and dissolution and its ownership in Liminal was distributed to its members and to the holders of incentive units. Immediately subsequent to the dissolution, all outstanding unvested incentive unit awards under 4Bionic's 2019 Equity Incentive Plan were replaced with preferred stock awards indexed to and settled in the preferred stock of the former 4Bionics subsidiaries Liminal, Detect, Inc. (f/k/a Homodeus Inc.), and identifeye HEALTH Inc. (f/k/a Tesseract Health, Inc.). The preferred stock awards are subject to service vesting conditions only. No incremental value was provided to participants as a result of the modification of the awards as the modification date fair value of the incentive unit awards was equal to modification date fair value of the stock underlying the restricted stock awards. Moreover, the remaining vesting period before and after modification was unchanged. No incremental compensation expense was recognized as a result of the modification.

Prior to the dissolution of 4Bionics, a portion of total 4Bionics stock-based compensation expense was allocated to Liminal based on the level of service provided by the relevant employees and nonemployees to Liminal over the term of the award. Subsequent to the dissolution of 4Bionics, the Company recognizes the stock-based compensation expense related to the replacement preferred stock awards and no allocation methodology is required. In connection with the Business Combination, all replacement preferred stock awards were accelerated to fully vest. The Company recognized stock-based compensation expense of $578 related to the incentive unit awards and replacement preferred stock awards during the years ended December 31, 2021.

Restricted Stock Units

The following table summarizes the changes in the Company's outstanding restricted stock units ("RSUs") for the year ended December 31, 2022:

	Number of RSUs
Outstanding at January 1, 2021	—
Granted	117,516
Released	—
Forfeited	—
Outstanding at December 31, 2021	117,516
Granted	2,493,335
Released	(319,557)
Forfeited	(694,514)
Expired	(11,421)
Outstanding at December 31, 2022	1,585,359

During the year ended December 31, 2022, the Company granted 2,493,335 RSUs to employees of the Company. The RSUs vest over a four year period, contingent on the ongoing service of the employees. The grant date fair value of the RSUs was measured using the fair value of the underlying Class A common stock, which had a prices ranging from $0.78 to $3.85 per share on the grant date. The total grant date fair value of $8,316 will be recognized evenly over the four year period as the service condition is satisfied.

The Company recognized $4,243 and $9 of share-based compensation expense, related to RSUs during the years ended December 31, 2022 and 2021. The weighted average grant date fair value per share of RSUs granted was $3.34 and $9.19 for the years ended December 31, 2022 and 2021, respectively. The aggregate fair market value of RSUs that vested during the year ended December 31, 2022 was $491.

(all amounts are in thousands, except share and per share data)

On June 27, 2022, David Scott delivered his resignation as the Company's President, Chief Executive Officer and member of the Board of Directors, effective as July 29, 2022. Pursuant to the terms of the Restricted Stock Unit Award Grant Notice and Agreement dated April 26, 2022 with Mr. Scott under the Hyperfine Plan, the 649,350 RSUs awarded on April 26, 2022, which were fully vested upon grant and the stock-based compensation expense for these fully vested awards were recognized immediately upon grant and will continue to remain outstanding until paid in accordance with the schedule set forth in the grant notice. In addition, 150,000 unvested RSUs and 3,124,252 unvested options held by Mr. Scott ceased to vest as of the resignation date of July 29, 2022 and were immediately forfeited. The previously recognized stock-based compensation expense of $4,501 related to these awards was recaptured in accordance with ASC 718 as a credit to general and administrative expense.

In December 2021, immediately following the Business Combination, the Company granted 117,516 restricted stock units ("RSUs") to members of the Company's Board of Directors. The RSUs vest over a three year period, contingent on the ongoing service of the Directors. The grant date fair value of the RSUs was measured using the fair value of the underlying Class A common stock, which was $9.19 per share on the grant date. The total grant date fair value of $1,080 will be recognized evenly over the three year period as the service condition is satisfied.

Earn-Out Shares

During the year ended December 31, 2022, no earnout shares were granted. During the year ended December 31, 2021, subject to the achievement of certain milestones, certain employees are entitled to a total of 933,933 Earn-Out Shares. These Earn-Out Shares fall within the scope of ASC 718, pursuant to which such Earn-Out Shares are equity classified and their grant date fair value will be recognized as compensation expense over the vesting period.

During the years ended December 31, 2022 and 2021, the Company recorded $2,926 and $288, respectively, of share-based compensation expense related to Earn-Out Shares.

Earn-out valuation inputs

The Company utilized a Monte Carlo Simulation pricing model for determining the estimated fair value for Earn-Out Shares. The fair value is based on the simulated price of the Company over the maturity date of the Earn-Out Shares. The key assumptions used in the valuation were as follows:

	2021
Stock Price	10.92
Risk Free interest rate	0.96%
Expected dividend yield	0.0%
Term (years)	3
Expected volatility	54.5%

Risk free interest rate

The risk free interest rate for periods within the expected term of the awards is based on the U.S. Treasury yield curve in effect at the time of the grant.

Expected dividend yield

The Company has never declared or paid any cash dividends and does not expect to pay any cash dividends in the foreseeable future.

Expected term

For Earn-Out Shares, the expected term is determined to be three years from the Closing as this is the period over which the market price milestone may be achieved. As there is no dependent vesting period, the shares are exercisable at the point that the market condition is reached.

(all amounts are in thousands, except share and per share data)

Expected volatility

As Legacy Hyperfine was privately held from inception through the Closing, there was no specific historical or implied volatility information available.

Accordingly, the Company estimates the expected volatility on the historical stock volatility of a group of similar companies that are publicly traded over a period equivalent to the expected term of the earn-out awards. A point estimate of expected annual equity volatility of 55% for December 31, 2021 was selected in the guideline companies' historical range.

Stock-Based Compensation Expense

The Company's stock-based compensation expense for the periods presented was as follows:

	2022	2021
Cost of sales	115	24
Research and development	2,141	1,327
General and administrative	8,064	5,482
Sales and marketing	332	68
Total stock-based compensation expense	**$ 10,652**	**$ 6,901**

Total unrecognized stock-based compensation expense as of December 31, 2022 was $10,074 which will be recognized over the remaining vesting period of 2.84 years.

11. NET LOSS PER SHARE

Basic net loss per share is computed by dividing the net loss by the weighted-average number of shares of common stock of the Company outstanding during the period. Diluted net loss per share is computed by giving effect to all common equivalent shares of the Company, including convertible preferred stock, outstanding stock options, RSUs and Earn-Out Shares, to the extent dilutive. Basic and diluted net loss per share was the same for each period presented as the inclusion of all common equivalent shares of the Company outstanding would have been anti-dilutive.

The following table presents the calculation of basic and diluted net loss per share for the Company's common stock:

	2022	2021
Numerator:		
Net Loss	$ (73,164)	$ (64,851)
Numerator for Basic and Dilutive net loss per share – Loss available to common stockholders	**$ (73,164)**	**$ (64,851)**
Denominator:		
Common Stock	70,449,191	3,690,523
Denominator for Basic and Dilutive net loss per share - Weighted-average common stock	**70,449,191**	**3,690,523**
Basic and dilutive net loss per share	**$ (1.04)**	**$ (17.57)**

(all amounts are in thousands, except share and per share data)

Since the Company was in a net loss position for all periods presented, the basic loss per share calculation excludes preferred stock as it does not participate in net losses of the Company. Additionally, net loss per share attributable to Class A and Class B common stockholders was the same on a basic and diluted basis, as the inclusion of all common equivalent shares outstanding would have been anti-dilutive. Anti-dilutive common equivalent shares were as follows:

	2022	2021
Outstanding options to purchase common stock	10,719,564	7,522,136
Outstanding RSUs	1,585,359	117,516
Earn-Out Shares [(1)]	9,421,444	10,000,000
Total anti-dilutive common equivalent shares	**21,726,367**	**17,639,652**

(1) The Company will issue to holders of Legacy Hyperfine and Liminal securities as of immediately prior to the effective time of the Mergers, in accordance with their pro rata share, up to 10,000,000 shares of Class A common stock as earn-out consideration (the “Earn-Out Shares”) net of forfeitures, if at any time during the period between the Closing Date of December 22, 2021 and the third anniversary of the Closing Date (the “Earn-Out Period”), (i) the last reported sale price of the Class A common stock is greater than or equal to $15.00 for any 20 trading days within any 30 consecutive trading day period, or (ii) there is a transaction that will result in shares of Class A common stock being converted or exchanged into the right to receive cash or other consideration having a value greater than or equal to $15.00. During the Earn-Out Period, if there is a transaction (other than for stock splits, stock dividends, special cash dividends, reorganizations, recapitalizations or similar transactions affecting the Class A common stock) that will result in the shares of Class A common stock being converted or exchanged into the right to receive cash or other consideration having a value less than $15.00, then the right to receive Earn-Out Shares will terminate.

12. INCOME TAXES

Significant components of the Company's deferred tax assets (liabilities) are as follows:

	As of December 31,	
	2022	2021
Gross deferred tax assets (liabilities):		
Net operating loss carryforwards	$ 39,033	$ 29,300
Tax credit carryforwards	5,478	3,429
Fixed assets	(117)	(117)
Stock-based compensation	2,621	1,634
Capitalized R&D	5,463	—
Deferred revenue	817	949
Accrued bonuses	—	857
Other	70	84
Total deferred tax assets	53,365	36,136
Valuation allowance	(53,365)	(36,136)
Net deferred tax assets (liabilities)	**$ —**	**$ —**

The Company had no income tax expense due to federal and state net operating losses incurred for the years ended December 31, 2022 and 2021. The Company has also not recorded any income tax benefits for its federal and state net operating losses incurred in each period due to uncertainty of realizing the benefit from those items. All of the Company’s losses before income taxes were generated in the United States. The effective tax rate for the Company for the years ended December 31, 2022 and 2021 was zero percent. A reconciliation of the income tax expense at the federal statutory tax rate to the Company’s effective income tax rate follows:

(all amounts are in thousands, except share and per share data)

	As of December 31,	
	2022	**2021**
Statutory tax rate	21.0 %	21.0 %
State taxes, net of federal benefit	2.1 %	4.0 %
Federal research and development credit	2.5 %	1.5 %
Stock-based compensation	(1.5)%	(0.1)%
Deferred tax adjustment resulting from tax rate change	(0.4)%	2.2 %
Other	(0.1)%	(0.5)%
Valuation allowance	(23.5)%	(28.1)%
Effective tax rate	**0.0 %**	**0.0 %**

The Company's effective tax rate for December 31, 2022 and 2021 differs from the federal statutory tax rate of 21% mainly due to the effect of deferred state income tax benefits resulting from state net operating loss carryforwards, the tax benefits related to federal and state research and development tax credits, and the effects of nondeductible stock based compensation. The net effect of these items is fully offset by the increase in the Company's valuation allowance from the prior year.

The Company has established a full valuation allowance against its net deferred tax assets due to the uncertainty of the Company's ability to generate sufficient taxable income to realize the deferred tax assets, and therefore has not recognized any benefits from the net operating losses, tax credits and other deferred tax assets. The Company's valuation allowance increased $18,135 and $18,348 for the years ended December 31, 2022 and 2021, respectively.

As of December 31, 2022, the Company had the following tax net operating loss carryforwards available to reduce future federal and state taxable income, and tax credit carryforwards available to offset future federal and state income taxes:

	Hyperfine	
	Amount	**Begin to Expire in**
Hyperfine tax net operating loss carryforwards:		
Federal (pre-2018 NOLs)	$ 12,084	2034
Federal (post-2017 NOLs)	132,748	No Expiration
States	84,977	2031
Tax credit carryforwards:		
Federal research and development	3,877	2034
Connecticut research and development	1,015	No Expiration
Connecticut others	21	5 Year Carryforward
Federal others	135	5 Year Carryforward

	Liminal	
	Amount	**Begin to Expire in**
Liminal tax net operating loss carryforwards:		
Federal (pre-2018 NOLs)	$ —	
Federal (post-2017 NOLs)	13,446	No Expiration
States	13,443	2038
Tax credit carryforwards:		
Federal research and development	717	2038
Connecticut research and development	81	No Expiration
Federal and state other	3	2025

Under Internal Revenue Code Section 382, if a corporation undergoes an "ownership change," the corporation's ability to use its pre-change net operating loss and tax credit carryforwards to offset its post-change income and tax liabilities may be limited. Generally, an ownership change occurs when certain shareholders increase their aggregated ownership by more than 50 percentage points over their lowest ownership percentage in a testing period (typically three years). The Company performed a Section 382 analysis in 2021 for Legacy Hyperfine to determine whether an

ownership change had occurred. Based on this analysis, Legacy Hyperfine experienced two consecutive ownership changes, one on January 17, 2017, and one on May 16, 2017. As a result, Legacy Hyperfine's net operating loss and tax credit carryforwards as of December 31, 2020 are subject to a Section 382 limitation. The January 17, 2017 ownership change resulted in an annual limitation of $865 and the May 16, 2017 ownership change resulted in an annual limitation of $3,008. The first (earlier) limitation will limit the deduction of pre-change losses and credits arising before the first ownership change. The second (later) ownership change creates another limit to deduction of those pre-change losses and credits. However, the second ownership change does not allow for a "step-up" of the first limitation and therefore the pre-January 17, 2017 losses and credits are still subject to the first limitation amount. Due to these limitations, the Company estimates that $3,125 and $249 of the federal net operating loss and research and development credit carryforwards, respectively, will expire before utilization. Accordingly, Legacy Hyperfine's gross deferred tax assets and corresponding valuation allowance have been adjusted to reflect the estimated expirations. In addition, as a result of the Business Combination and any other equity issuances since the last ownership change, the Company may have experienced additional ownership changes as of December 31, 2022. As of December 31, 2022, the Company has not completed an additional Section 382 analysis to determine whether any successive ownership changes have occurred.

The Company has adopted the accounting guidance within ASC Topic 740 on uncertainties in income taxes. ASC Topic 740 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return.

As of December 31, 2022 and 2021, the Company did not have any unrecognized tax benefits. To the extent penalties and interest would be assessed on any underpayment of income tax, the Company's policy is that such amounts would be accrued and classified as a component of income tax expense in the combined and consolidated financial statements. To date, the Company has not recorded any such interest or penalties.

The Company files income tax returns in the U.S. federal and various state jurisdictions. As a result of the Company's net operating loss carryforwards, the Company's federal and state statutes of limitations generally remain open for all tax years until its net operating loss and tax credit carryforwards are utilized or expire prior to utilization. The Company does not currently have any federal or state income tax examinations in progress.

Additionally, as a result of legislation in the state of Connecticut, companies have the opportunity to exchange certain research and development tax credit carryforwards for a cash payment of 65% of the research and development tax credit. The research and development expenses that qualify for Connecticut credits are limited to those costs incurred within Connecticut. The Company has elected to participate in the exchange program and, as a result, has recognized net benefits of $468 and $103 for the years ended December 31, 2022 and 2021, respectively, which is included in research and development expenses in the accompanying statements of operations and comprehensive loss. As of December 31, 2022 and 2021, the Company has recorded $525 and $196 of the research and development tax credit receivables in Prepaid expenses and other current assets on the Company's combined and consolidated balance sheets, respectively.

13. RELATED PARTY TRANSACTIONS

The Company utilizes and subleases office and lab space in Connecticut which is being leased from an unrelated landlord by 4Catalyzer Corporation, ("4C"), which is owned by a related party. The Company pays rent to 4C on a month-to-month basis, and no lease agreement was entered into between the parties until June 2021. A total of approximately $314 and $149 was paid during 2022 and 2021, respectively.

Prior to 4Bionics executing a plan of liquidation and dissolution on April 2, 2021, certain expenses incurred at 4Bionics were allocated to its subsidiaries, including Liminal. Expenses that broadly benefited 4Bionics and its subsidiaries were allocated evenly amongst its three subsidiaries. Expenses that were incurred on behalf of the employees of each company were allocated based on each subsidiary's relative headcount. Total proceeds allocated to Liminal upon liquidation and dissolution in 2021 were $101. The method used to allocate common expenses of 4Bionics to Liminal is reasonable.

In January 2018, the Company entered into a Promissory Note (the "Note") with one of its employees (the "Borrower") in the amount of $90. The Note bore interest at a rate equal to 1.68% per annum. In accordance with the terms of the Note, since the Borrower remained employed with the Company on the maturity date of January 11, 2022, $90 of the then outstanding principal amount and all interest accrued to that date was forgiven and the Borrower is no longer required to repay the amount..

The Company also made payments to 4C to prefund the acquisition of capital assets and these amounts are included in Other assets — related party on the combined and consolidated balance sheets. There were no prepaid advances as of December 31, 2022 and 2021. During 2021, the Company wrote off $983 of such prepaid advances considered to be unrecoverable.

The Company was a party to an Amended and Restated Technology Services Agreement (the "ARTSA"), most recently amended on November 11, 2020, by and among 4C, the Company and other participant companies controlled by the Rothberg family. Under the ARTSA, the Company and the other participant companies agreed to share certain non-core technologies, which means any technologies, information or equipment owned or otherwise controlled by the participant company that are not specifically related to the core business area of the participant and subject to certain restrictions on use. The ARTSA also provided for 4C to perform certain services for the Company and each other participant company such as monthly administrative, management and technical consulting services to the Company which are pre-funded approximately once a quarter. The Company incurred expenses from 4C of $33 and $4,055 during the years ended December 31, 2022 and 2021, respectively. As of December 31, 2022 there was $48 due from 4C and as of December 31, 2021 there was $1,872 due to 4C for expenses paid on their behalf. These receivables and payables are included in Due from related parties and Due to related parties, respectively, on the combined and consolidated balance sheets. On July 7, 2021, Legacy Hyperfine, Liminal and 4C entered into First Addendums to the ARTSA, pursuant to which Legacy Hyperfine and Liminal each terminated its participation under the ARTSA immediately prior to the Closing. Legacy Hyperfine and Liminal each entered into a Master Services Agreement (the "Master Services Agreements") with 4C effective as of July 7, 2021 pursuant to which Legacy Hyperfine and Liminal may engage 4C to provide services such as general administration, facilities, information technology, financing, legal, human resources and other services, through future statements of work and under terms and conditions to be determined by the parties with respect to any services to be provided.

The ARTSA also provided for the participant companies to provide other services to each other. The Company also has transactions with other entities under common ownership, which include payments made to third parties on behalf of the Company. The amounts remaining payable at December 31, 2022 and 2021 are $0 and $110, respectively, and are included in the Due to related parties on the combined and consolidated balance sheets. In addition, the Company has transactions with these other entities under common ownership which include payments made by the Company to third parties on behalf of the other entities and the amounts remaining receivable are in the aggregate $0 at December 31, 2022 and the amounts remaining receivable are in the aggregate $14 at December 31, 2021, and are reflected in the Due from related parties on the combined and consolidated balance sheets. All amounts are paid or received throughout the year within 30 days after the end of each month.

Legacy Hyperfine and Liminal entered into Technology and Services Exchange Agreements (each, a "TSEA" and collectively, the "TSEA") with other participant companies controlled by the Rothbergs. A TSEA by and among Butterfly Network, Inc., AI Therapeutics, Inc., Quantum-Si Incorporated, 4Bionics, identifeye HEALTH Inc. (f/k/a Tesseract Health, Inc.), Detect, Inc. (f/k/a Homodeus Inc.), Legacy Hyperfine and Liminal was signed in November 2020; a TSEA by and among Quantum-Si Incorporated, AI Therapeutics, Inc., 4Bionics, identifeye HEALTH Inc., Detect, Inc., Legacy Hyperfine and Liminal was signed in February 2021 (and which Protein Evolution, Inc. joined in August 2021); and a TSEA by and among Legacy Hyperfine, Liminal, AI Therapeutics, Inc., identifeye HEALTH Inc. and Detect, Inc. was signed in July 2021 and is effective upon the Closing. Under the TSEA, Legacy Hyperfine, Liminal and other participant companies may, in their discretion, permit the use of non-core technologies, which include any technologies, information or equipment owned or otherwise controlled by the participant company that are not specifically related to the core business area of the participant, such as software, hardware, electronics, fabrication and supplier information, vendor lists and contractor lists, by other participant companies. As of December 31, 2022 and 2021, the Company had transactions with other participant companies and had expenses of $0 and $11, respectively, included in Accounts payable.

14. COMMITMENTS AND CONTINGENCIES

Commitments

During 2020, the Company was awarded a $1,610 grant from the BMGF for the provision and equipping of 20 sites with the Hyperfine portable point-of-care MRI system to enable the performance of a multi-site study focused on optimizing diagnostic image quality (the "Project"). During 2021, the Company was awarded an additional $3,300 grant from the BMGF, of which $2,500 was received for the provision and equipping of five sites and other related deliverables, of which the remaining $800 was received in the second quarter of 2022. The funds are accounted for as restricted cash with an offset to deferred grant revenue. At December 31, 2022 and 2021, the Company has $771 and $2,662, respectively, in restricted cash and deferred grant funding on the combined and consolidated balance sheets. Any grant funds, plus any income, that have not been used for, or committed to, the project must be returned promptly to BMGF upon expiration of or termination of the agreement. Both of the grants are designed to support the deployment of a total of 25 Swoop® systems and other services to investigators, which commenced in the spring of 2021, and is expected to fund the program for approximately two years. At December 31, 2022, 20 Swoop® system units and 10 baby cradles were provisioned and delivered to BMGF and the majority of the milestones for service deliverables were also met. These grants are designed to provide data to validate the use of our Swoop® system in measuring the impact of maternal anemia, malnutrition, infection and birth related injury.

Contingencies

The Company does not have any outstanding or ongoing litigation and legal matters where, based on present information, including its assessment of the merits of the particular claims, the Company believes it is reasonably possible that any asserted or unasserted legal claims or proceedings, individually or in aggregate, will have a material adverse effect on its results of operations or financial condition. The ultimate outcome of any legal matter cannot be predicted with certainty.

The Company has indemnification obligations under some agreements that the Company enters into with other parties in the ordinary course of business, including business partners, investors, contractors, and the Company's officers, directors and certain employees. The Company has agreed to indemnify and defend the indemnified party claims and related losses suffered or incurred by the indemnified party from actual or threatened third-party claim because of the Company's activities or non-compliance with certain representations and warranties made by the Company. It is not possible to determine the maximum potential loss under these indemnification provisions due to the Company's limited history of prior indemnification claims and the unique facts and circumstances involved in any particular case. To date, losses recorded in the combined and consolidated statements of operations and comprehensive loss in connection with the indemnification provisions have not been material.

The Company agreed to pay $1,000 to a third-party service provider upon the receipt by the Companies' pre-closing equity holders of any Earn-Out Shares (see Note 3. *Business Combination*). The Company determined the probability of such payment to be not probable thus no liability was recognized.

15. RESTRUCTURING

During the quarter ended December 31, 2022, the Company initiated and carried out certain restructuring actions in order to reduce costs and improve efficiency. As a result, the Company recognized $1,002 of costs primarily related to employee termination expenses and losses from fixed assets impairment. The Company recognized $80 in impairment related to the research and development asset as the Company abandoned further development efforts. On the

statement of operations, the associated restructuring costs were presented in operating expenses. On the combined and consolidated statement of cash flows, the amounts were presented in the captions in which such amounts would have been recorded absent the impairment charges. As of December 31, 2022, there was $832 of accrued liability related to employee termination expenses.

Exhibit 4.2

DESCRIPTION OF THE REGISTRANT'S SECURITIES

The following summary of the material terms of the capital stock of Hyperfine, Inc. (formerly HealthCor Catalio Acquisition Corp.) is not intended to be a complete summary of the rights and preferences of such securities, and is qualified by reference to our Certificate of Incorporation, as amended (the "Charter"), and our Bylaws (the "Bylaws"), each of which are incorporated by reference as an exhibit to the Annual Report on Form 10-K of which this Exhibit is a part, and certain provisions of Delaware law. We urge you to read each of our Charter and our Bylaws in their entirety for a complete description of the rights and preferences of our securities. Unless the context requires otherwise, all references to "we", "us," "our," the "Company" and "Hyperfine" in this section refer solely to Hyperfine, Inc. (formerly HealthCor Catalio Acquisition Corp.) and not to our subsidiaries.

Authorized Capital Stock

We are authorized to issue 628,000,000 shares, consisting of 600,000,000 shares of Class A common stock, par value $0.0001 per share, 27,000,000 shares of Class B common stock, par value $0.0001 per share, and 1,000,000 shares of preferred stock, par value $0.0001 per share.

Common Stock

Class A Common Stock

Voting Rights

Holders of Class A common stock are entitled to cast one vote per share. Generally, holders of all classes of common stock vote together as a single class, and an action is approved by stockholders if a majority of votes cast affirmatively or negatively on the action are cast in favor of the action. In any election by stockholders of directors other than in a contested election, directors are elected by the affirmative vote of a majority of the votes cast in favor or against the election of a nominee, while in a contested election, directors are elected by a plurality of the votes cast. Holders of Class A common stock are not entitled to cumulate their votes in the election of directors.

Dividend Rights

With limited exceptions in the case of certain stock dividends or disparate dividends approved by the affirmative vote of the holders of a majority of the Class A common stock and Class B common stock, each voting separately as a class, holders of Class A common stock will share ratably (based on the number of shares of Class A common stock held), together with each holder of Class B common stock, if and when any dividend is declared by our board of directors out of funds legally available therefor, subject to restrictions, whether statutory or contractual (including with respect to any outstanding indebtedness), on the declaration and payment of dividends and to any restrictions on the payment of dividends imposed by the terms of any outstanding preferred stock or any class or series of stock having a preference over, or the right to participate with, the Class A common stock with respect to the payment of dividends.

Liquidation, Dissolution and Winding Up

On the liquidation, dissolution, distribution of assets or winding up of Hyperfine, each holder of Class A common stock, together with each holder of Class B common stock, will be entitled, pro rata on a per share basis, to all assets of Hyperfine of whatever kind available for distribution to the holders of common stock, subject to the designations, preferences, limitations, restrictions and relative rights of any other class or series of preferred stock of Hyperfine then outstanding and unless disparate or different treatment of the shares of Class A common stock and Class B common stock is approved by the affirmative vote of the holders of a majority of the outstanding shares of Class A common stock and Class B common stock, each voting separately as a class.

Other Matters

Holders of shares of Class A common stock do not have subscription, redemption or conversion rights. All of the outstanding shares of Class A common stock are validly issued, fully paid and non-assessable.

Class B Common Stock

Voting Rights

Holders of Class B common stock are entitled to cast 20 votes per share of Class B common stock. Generally, holders of all classes of our common stock vote together as a single class, and an action is approved by our stockholders if a majority of votes cast affirmatively or negatively on the action are cast in favor of the action. In any election by stockholders of directors other than in a contested election, directors are elected by the affirmative vote of a majority of the votes cast in favor or against the election of a nominee, while in a contested election, directors are elected by a plurality of the votes cast. Holders of Class B common stock will not be entitled to cumulate their votes in the election of directors.

Dividend Rights

With limited exceptions in the case of certain stock dividends or disparate dividends approved by the affirmative vote of the holders of a majority of the Class A common stock and Class B common stock, each voting separately as a class, holders of Class B common stock will share ratably (based on the number of shares of Class B common stock held), together with each holder of Class A common stock, if and when any dividend is declared by our board of directors out of funds legally available therefor, subject to restrictions, whether statutory or contractual (including with respect to any outstanding indebtedness), on the declaration and payment of dividends and to any restrictions on the payment of dividends imposed by the terms of any outstanding preferred stock or any class or series of stock having a preference over, or the right to participate with, the Class B common stock with respect to the payment of dividends.

Optional Conversion

Holders of Class B common stock have the right to convert shares of their Class B common stock into fully paid and non-assessable shares of Class A common stock, on a one-to-one basis, at the option of the holder at any time upon written notice to us.

Mandatory Conversion

Holders of Class B common stock can have their shares of Class B common stock automatically converted into shares of Class A common stock, on a one-to-one basis, upon the occurrence of any of the events described below:

(1) Any sale, assignment, transfer, conveyance, hypothecation, or other transfer or disposition, directly or indirectly, of any shares of Class B common stock or any legal or beneficial interest in such shares, whether or not for value and whether voluntary or involuntary or by operation of law (including by merger, consolidation, or otherwise), including, without limitation the transfer of shares of Class B common stock to a broker or other nominee or the transfer of, or entering into a binding agreement with respect to, voting control over such shares by proxy or otherwise, other than a permitted transfer.

(2) Upon the first date on which Jonathan M. Rothberg, Ph.D., together with all other qualified stockholders, collectively cease to beneficially own at least 20% of the number of Class B common stock (as such number of shares is equitably adjusted in respect of any reclassification, stock dividend, subdivision, combination, or recapitalization of the Class B common stock) collectively beneficially owned by Dr. Rothberg and permitted transferees of Class B common stock as of the Closing.

(3) Upon the date specified by the affirmative vote of the holders of at least two-thirds (2/3) of the outstanding shares of Class B common stock, voting as a separate class.

Liquidation Rights, Dissolution and Winding Up

On the liquidation, dissolution, distribution of assets or winding up of Hyperfine, each holder of Class B common stock, together with each holder of Class A common stock, will be entitled, pro rata on a per share basis, to all assets of Hyperfine of whatever kind available for distribution to the holders of common stock, subject to the designations, preferences, limitations, restrictions and relative rights of any other class or series of preferred stock of Hyperfine then outstanding and unless disparate or different treatment of the shares of Class A common stock and Class B common stock is approved by the affirmative vote of the holders of a majority of the outstanding shares of Class A common stock and Class B common stock, each voting separately as a class.

Preferred Stock

Our Charter provides that our board of directors has the authority, without action by the stockholders, to designate and issue shares of preferred stock in one or more classes or series, and the number of shares constituting any such class or series, and to fix the voting powers, designations, preferences, limitations, restrictions and relative rights of each class or series of preferred stock, including, without limitation, dividend rights, conversion rights, voting rights, redemption privileges and liquidation preferences. There were no shares of preferred stock outstanding as of December 31, 2022.

The purpose of authorizing our board of directors to issue preferred stock and determine the rights and preferences of any classes or series of preferred stock is to eliminate delays associated with a stockholder vote on specific issuances. The simplified issuance of preferred stock, while providing flexibility in connection with possible acquisitions, future financings and other corporate purposes, could have the effect of making it more difficult for a third party to acquire, or could discourage a third party from seeking to acquire, a majority of our outstanding voting stock. Additionally, the issuance of preferred stock may adversely affect the holders of our common stock by restricting dividends on our common stock, diluting the voting power of our common stock or subordinating the dividend or liquidation rights of our common stock. As a result of these or other factors, the issuance of preferred stock could have an adverse impact on the market price of our common stock.

In December 2021, we completed the transactions (the “Business Combination”) contemplated by that certain Business Combination Agreement, dated as of July 7, 2021 (the “Business Combination Agreement”), by and among HealthCor Catalio Acquisition Corp., a blank check company incorporated as a Cayman Islands exempted company with limited liability (“HealthCor”), Optimus Merger Sub I, Inc., a Delaware corporation and wholly owned subsidiary of HealthCor (“Merger Sub I”), Optimus Merger Sub II, Inc., a Delaware corporation and wholly owned subsidiary of HealthCor (“Merger Sub II”), Hyperfine, Inc., a Delaware corporation (“Legacy Hyperfine”), and Liminal Sciences, Inc., a Delaware corporation (“Liminal”). On December 22, 2021, immediately upon the consummation of the Business Combination, and such completion, the “Closing”), Merger Sub I merged with and into Legacy Hyperfine (the “Hyperfine Merger”), with Hyperfine surviving the Hyperfine Merger as a wholly owned subsidiary of HealthCor, and Merger Sub II merged with and into Liminal (the “Liminal Merger”, and together with the Hyperfine Merger, the “Mergers”), with Liminal surviving the Liminal Merger as a wholly owned subsidiary of HealthCor. In connection with the Business Combination, HealthCor changed its name to “Hyperfine, Inc.,” Legacy Hyperfine changed its name to “Hyperfine Operations, Inc.” and Liminal changed its name to “Liminal Operations, Inc.” and subsequently to "Liminal Sciences, Inc."

As a consequence of the Mergers, at the effective time of the Mergers (“Effective Time”), (i) each share of Legacy Hyperfine capital stock (other than shares of Legacy Hyperfine Series A preferred stock) that was issued and outstanding as of immediately prior to the Effective Time was automatically cancelled and extinguished and converted into the right to receive a number of shares of the Company’s Class A common stock equal to 0.3275 (the “Hyperfine Exchange Ratio”), rounded down to the nearest whole number of shares; (ii) each share of Legacy Hyperfine Series A preferred stock that was issued and outstanding as of immediately prior to the Effective Time was automatically cancelled and extinguished and converted into the right to receive a number of shares of the Company’s Class B common stock equal to the Hyperfine Exchange Ratio, rounded down to the nearest whole number of shares; (iii) each share of Liminal capital stock (other than shares of Liminal Series A-1 preferred stock) that was issued and outstanding as of immediately prior to the Effective Time was automatically cancelled and extinguished and converted into the right to receive a number of shares of the Company’s Class A common stock equal to 0.1796 (the “Liminal Exchange Ratio”), rounded down to the nearest whole number of shares; (iv) each share of Liminal Series A-1 preferred stock that was issued and outstanding as of immediately prior to the Effective

Time was automatically cancelled and extinguished and converted into the right to receive a number of shares of the Company's Class B common stock equal to the Liminal Exchange Ratio, rounded down to the nearest whole number of shares; (v) each option to purchase shares of Legacy Hyperfine common stock and each option to purchase shares of Liminal common stock, whether vested or unvested, that was outstanding and unexercised as of immediately prior to the Effective Time was assumed by the Company and became an option (vested or unvested, as applicable) to purchase a number of shares of the Company's Class A common stock equal to the number of shares of Legacy Hyperfine common stock or Liminal common stock subject to such option immediately prior to the Effective Time multiplied by the Hyperfine Exchange Ratio or the Liminal Exchange Ratio, as applicable, rounded down to the nearest whole number of shares, at an exercise price per share equal to the exercise price per share of such option immediately prior to the Effective Time divided by the Hyperfine Exchange Ratio or the Liminal Exchange Ratio, as applicable, rounded up to the nearest whole cent; and (vi) each Legacy Hyperfine restricted stock unit and each Liminal restricted stock unit outstanding immediately prior to the Effective Time was assumed by the Company and became a restricted stock unit with respect to a number of shares of the Company's Class A common stock equal to the number of shares of Legacy Hyperfine common stock or Liminal common stock subject to such Legacy Hyperfine restricted stock unit or Liminal restricted stock unit immediately prior to the Effective Time multiplied by the Hyperfine Exchange Ratio or the Liminal Exchange Ratio, as applicable, rounded down to the nearest whole share.

Exclusive Forum

Our Charter provides that, to the fullest extent permitted by law, unless we otherwise consent in writing, the Court of Chancery (the "Chancery Court") of the State of Delaware (or, in the event that the Chancery Court does not have jurisdiction, the federal district court for the District of Delaware or other state courts of the State of Delaware) shall, to the fullest extent permitted by law, be the sole and exclusive forum for (1) any derivative action or proceeding brought on behalf of Hyperfine, (2) any action asserting a claim of breach of a fiduciary duty owed by, or any other wrongdoing by, any current or former director, officer, other employee or stockholder of Hyperfine, (3) any action asserting a claim against us arising pursuant to any provision of the Delaware General Corporation Law ("DGCL"), our Charter or Bylaws, or as to which the DGCL confers jurisdiction on the Court of Chancery, (4) any action to interpret, apply, enforce or determine the validity of any provisions of our Charter or Bylaws, or (5) any other action asserting a claim governed by the internal affairs doctrine. Notwithstanding the foregoing, the federal district courts of the United States shall be the exclusive forum for the resolution of any action, suit or proceeding asserting a cause of action arising under the Securities Act of 1933, as amended (the "Securities Act") and the provisions of our Charter described above will not apply to claims arising under the Exchange Act or other federal securities laws for which there is exclusive federal jurisdiction.

Anti-Takeover Effects of Provisions of our Charter, Bylaws and Applicable Law

Certain provisions of our Charter, Bylaws, and laws of the State of Delaware, where we are incorporated, may discourage or make more difficult a takeover attempt that a stockholder might consider in his or her best interest. These provisions may also adversely affect prevailing market prices for the Class A common stock and the Class B common stock. We believe that the benefits of increased protection give us the potential ability to negotiate with the proponent of an unsolicited proposal to acquire or restructure us and outweigh the disadvantage of discouraging those proposals because negotiation of the proposals could result in an improvement of their terms.

Authorized but Unissued Shares

Delaware law does not require stockholder approval for any issuance of authorized shares. However, the listing requirements of The Nasdaq Stock Market, which apply so long as the Class A common stock remains listed on The Nasdaq Stock Market, require stockholder approval of certain issuances equal to or exceeding 20% of the then outstanding voting power or then outstanding number of shares of common stock. Additional shares that may be issued in the future may be issued for a variety of corporate purposes, including future public offerings, to raise additional capital, or to facilitate acquisitions. The existence of authorized but unissued and unreserved common stock and preferred stock could make more difficult or discourage an attempt to obtain control of Hyperfine by means of a proxy contest, tender offer, merger, or otherwise.

Dual Class Stock

As described above, our Charter provides for a dual class common stock structure which provides Dr. Rothberg with the ability to control the outcome of matters requiring stockholder approval, even though he owns significantly less than a majority of the shares of our outstanding common stock, including the election of directors and significant corporate transactions, such as a merger or other sale of Hyperfine or its assets.

Blank Check Preferred Stock

Our Charter provides for 1,000,000 authorized shares of preferred stock. The existence of authorized but unissued shares of preferred stock may enable our board of directors to render more difficult or to discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise. For example, if in the due exercise of its fiduciary obligations, our board of directors were to determine that a takeover proposal is not in the best interests of Hyperfine or our stockholders, our board of directors could cause shares of preferred stock to be issued without stockholder approval in one or more private offerings or other transactions that might dilute the voting or other rights of the proposed acquirer or insurgent stockholder or stockholder group. In this regard, our Charter grants our board of directors broad power to establish the rights and preferences of authorized and unissued shares of preferred stock. The issuance of shares of preferred stock could decrease the amount of earnings and assets available for distribution to holders of shares of common stock. The issuance may also adversely affect the rights and powers, including voting rights, of the holders of shares of common stock and may have the effect of delaying, deterring or preventing a change in control of Hyperfine.

Number of Directors

Our Charter and Bylaws provide that, subject to any rights of holders of preferred stock to elect additional directors under specified circumstances, the number of directors may be fixed from time to time solely pursuant to a resolution adopted by our board of directors; *provided, however,* that prior to the first date on which the issued and outstanding shares of Class B common stock represent less than 50% of the voting power of the then outstanding shares of our capital stock that would be entitled to vote for the election of directors at an annual meeting of stockholders, unless approved by the holders of a majority in voting power of the shares of our capital stock that would then be entitled to vote in the election of directors at an annual meeting or by written consent, the number of directors may not exceed nine.

Requirements for Advance Notification of Stockholder Meetings, Nominations and Proposals

Our Bylaws establish advance notice procedures with respect to stockholder proposals and nomination of candidates for election as directors, other than nominations made by or at the direction of our board of directors or a committee of the board. In order to be "properly brought" before a meeting, a stockholder will have to comply with advance notice requirements and provide us with certain information. Generally, to be timely, a stockholder's notice must be delivered to, or mailed and received at our principal executive offices not less than 90 days nor more than 120 days prior to the first anniversary of the immediately preceding annual meeting of stockholders. Our Bylaws also specify requirements as to the form and content of a stockholder's notice. Our Bylaws allow the chairperson of the meeting at a meeting of the stockholders to determine whether a proposal to the meeting was properly brought and to adopt rules and regulations for the conduct of meetings, except to the extent inconsistent with such rules, regulations and procedures as adopted by our board of directors, which may have the effect of precluding the conduct of certain business at a meeting if the rules and regulations are not followed. These provisions may also defer, delay, or discourage a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to influence or obtain control of Hyperfine.

Limitations on Stockholder Action by Written Consent

Our Charter provides that, subject to the terms of any series of our preferred stock, any action required or permitted to be taken by our stockholders must be effected at an annual or special meeting of the stockholders and may not be effected by written consent in lieu of a meeting; *provided*, *however*, that prior to the first date on which the issued and outstanding shares of Class B common stock represent less than 50% of the voting power of the then outstanding shares of our capital stock that would then be entitled to vote for the election of directors, any action required or permitted to be taken at any annual or special meeting of our stockholders, may be taken by written

consent if such written consent is signed by the holders of the outstanding stock having not less than the minimum number of votes that would be necessary to authorize or take such action at a meeting at which all shares entitled to vote on such matter were present and voted.

Amendment of our Charter and Bylaws

The DGCL provides generally that the affirmative vote of a majority of the outstanding shares entitled to vote thereon, voting together a single class, is required to amend a corporation's certificate of incorporation, unless the certificate of incorporation requires a greater percentage.

Our Charter provides that it may be amended by us in the manner provided therein or prescribed by statute. Our Charter provides that the affirmative vote of the holders of a majority of the voting power of the then-outstanding shares of our capital stock entitled to vote generally in the election of directors, voting together as a single class, will be required to amend or repeal any provision of our Charter, or adopt any provision of our Charter inconsistent therewith.

If any of the Class B common stock shares are outstanding, in addition to any vote required by Delaware law, the affirmative vote of the holders of two-thirds (2/3) of the outstanding shares of Class B common stock, voting as a separate class, is required to amend our Charter (1) in a manner that changes any of the voting, conversion, dividend or liquidation provisions of the shares of Class B common stock, (2) to provide for each share of Class A common stock or any preferred stock to have more than one vote per share or any rights to a separate class vote of the holders of shares of Class A common stock other than as provided by our Charter or required by the DGCL, or (3) to otherwise adversely impact the rights, powers, preferences or privileges of the shares of Class B common stock in a manner that is disparate from the manner in which it affects the rights, powers, preferences or privileges of the shares of Class A common stock.

If any shares of the Class A common stock shares are outstanding, we will not, without the prior affirmative vote of the holders of a majority of the outstanding shares of Class A common stock, voting as a separate class, in addition to any other vote required by applicable law or our Charter, directly or indirectly, whether by amendment, or through merger, recapitalization, consolidation or otherwise amend, alter, change, repeal or adopt any provision of our Charter (1) in a manner that is inconsistent with, or that otherwise alters or changes the powers, preferences, or special rights of the shares of Class A common stock so as to affect them adversely; or (2) to provide for each share of Class B common stock to have more than 20 votes per share or any rights to a separate class vote of the holders of shares of Class B common stock other than as provided by our Charter or required by the DGCL.
Our Charter also provides that our board of directors will have the power to adopt, amend, alter, or repeal our Bylaws by the affirmative vote of a majority of the directors present at any regular or special meeting of our board of directors at which a quorum is present in any manner not inconsistent with the laws of the State of Delaware or our Charter. Our stockholders are prohibited from adopting, amending, altering, or repealing Bylaws, or to adopt any provision inconsistent with Bylaws, unless such action is approved, in addition to any other vote required by our Charter, (i) when the issued and outstanding shares of Class B common stock represents less than 50% of the voting power of the then outstanding shares of capital stock that would be entitled to vote for the election of directors, the affirmative vote of the holders of at least two-thirds of the voting power of the capital stock that would be entitled to vote in the election of directors or, prior to such time, (ii) the affirmative vote of the holders of a majority of the voting power of the shares of capital stock that would be entitled to vote in the election of directors.

Business Combinations

Under Section 203 of the DGCL, a corporation will not be permitted to engage in a business combination with any interested stockholder for a period of three years following the time that such interested stockholder became an interested stockholder, unless:

(1) prior to such time the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;

(2) upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the

transaction commenced, excluding for purposes of determining the voting stock outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned (i) by persons who are directors and also officers and (ii) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or

(3) at or subsequent to such time the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2⁄3% of the outstanding voting stock which is not owned by the interested stockholder.

Generally, a "business combination" includes a merger, asset or stock sale or other transaction resulting in a financial benefit to the interested stockholder. Subject to certain exceptions, an "interested stockholder" is a person who, together with that person's affiliates and associates, owns, or within the previous three years owned, 15% or more of our outstanding voting stock. For purposes of this section only, "voting stock" has the meaning given to it in Section 203 of the DGCL.

Since we have not opted out of Section 203 of the DGCL, it will apply to us. As a result, this provision will make it more difficult for a person who would be an "interested stockholder" to effect various business combinations with us for a three-year period. This provision may encourage companies interested in acquiring us to negotiate in advance with our board of directors because the stockholder approval requirement would be avoided if our board of directors approves either the business combination or the transaction which results in the stockholder becoming an interested stockholder. These provisions also may have the effect of preventing changes in our board of directors and may make it more difficult to accomplish transactions, which stockholders may otherwise deem to be in their best interests.

Cumulative Voting

Under Delaware law, the right to vote cumulatively does not exist unless the charter specifically authorizes cumulative voting. Our Charter does not authorize cumulative voting.

Limitations on Liability and Indemnification of Officers and Directors

The DGCL authorizes corporations to limit or eliminate the personal liability of directors or officers of corporations and their stockholders for monetary damages for breaches of directors' or officers' fiduciary duties, subject to certain exceptions. Our Charter includes a provision that eliminates the personal liability of directors for damages for any breach of fiduciary duty as a director where, in civil proceedings, the person acted in good faith and in a manner that person reasonably believed to be in or not opposed to the best interests of Hyperfine or, in criminal proceedings, where the person had no reasonable cause to believe that his or her conduct was unlawful.

Our Charter provides that we may indemnify and advance expenses to our directors, officers, employees or agents to the fullest extent permitted by law. Our Bylaws provide that we shall indemnify and advance expenses to our directors and officers to the fullest extent authorized by the DGCL. We are also expressly authorized to carry directors' and officers' liability insurance providing indemnification for our directors, officers, and certain employees for some liabilities. We believe that these indemnification and advancement provisions and insurance are useful to attract and retain qualified directors and executive officers.

The limitation of liability, advancement and indemnification provisions in our Charter and Bylaws may discourage stockholders from bringing lawsuits against directors for any alleged breach of their fiduciary duty. These provisions also may have the effect of reducing the likelihood of derivative litigation against directors and officers, even though such an action, if successful, might otherwise benefit us and our stockholders. In addition, your investment may be adversely affected to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions.

There is currently no pending material litigation or proceeding involving any of our directors, officers, or employees for which indemnification is sought.

Corporate Opportunities

Our Charter provides for the renouncement by us of any interest or expectancy of Hyperfine in, or being offered an opportunity to participate in any matter, transaction, or interest that is presented to, or acquired, created, or developed by, or which otherwise comes into possession of, any director of Hyperfine who is not an employee of Hyperfine or any of its subsidiaries, unless such matter, transaction, or interest is presented to, or acquired, created, or developed by, or otherwise comes into the possession of a director of Hyperfine expressly and solely in that director's capacity as a director of Hyperfine.

Dissenters' Rights of Appraisal and Payment

Under the DGCL, with certain exceptions, our stockholders will have appraisal rights in connection with a merger or consolidation of Hyperfine. Pursuant to the DGCL, stockholders who properly request and perfect appraisal rights in connection with such merger or consolidation will have the right to receive payment of the fair value of their shares as determined by the Delaware Court of Chancery.

Stockholders' Derivative Actions

Under the DGCL, any of our stockholders may bring an action in our name to procure a judgment in our favor, also known as a derivative action, provided that the stockholder bringing the action is a holder of our shares at the time of the transaction to which the action relates or such stockholder's stock thereafter devolved by operation of law.

Registration Rights

Pursuant to Subscription Agreements that HealthCor entered into with certain institutional investors and accredited investors (the "PIPE Investors") in connection with the execution of the Business Combination Agreement on July 7, 2021, the PIPE Investors purchased HealthCor Class A ordinary shares immediately prior to the closing of the Business Combination (the "PIPE Investment") and the PIPE Investors are entitled to certain registration rights. Pursuant to the Letter Agreement with Jefferies LLC (the "Letter Agreement"), Hyperfine issued shares of Class A common stock (the "Letter Agreement Shares") to Jefferies LLC in lieu of deferred underwriting compensation relating to HealthCor's initial public offering and Jefferies LLC is entitled to certain registration rights. In particular, under the Subscription Agreements and the Letter Agreement, Hyperfine agreed to, within 45 calendar days after the closing of the Business Combination, file with the Securities and Exchange Commission ("SEC") (at Hyperfine's sole cost and expense) a registration statement registering the resale of the shares of Class A common stock issued to the PIPE Investors and pursuant to the Letter Agreement, and to use its commercially reasonable efforts to have such registration statement declared effective as soon as practicable after the filing thereof, but no later than the earlier of (i) the 45th calendar day (or 60th calendar day if the SEC notifies Hyperfine that it will "review" such registration statement) following the closing of the Business Combination and (ii) the 10th business day after the date Hyperfine is notified (orally or in writing) by the SEC that such registration statement will not be "reviewed" or will not be subject to further review. The registration statement was initially filed on January 24, 2022 and initially declared effective by the SEC on February 1, 2022. The post-effective amendment to the registration statement filed on January 24, 2023 was declared effective by the SEC on January 30, 2023.

At the Closing, Hyperfine, the Sponsor, certain affiliates of the Sponsor (the "Sponsor Group Holders") and certain Legacy Hyperfine equityholders and Liminal equityholders (the "Legacy Hyperfine Holders") entered into an amended and restated registration rights agreement (the "Registration Rights Agreement"), pursuant to which, among other things, the parties to the Registration Rights Agreement agreed not to effect any sale or distribution of any equity securities of Hyperfine held by any of them (except with respect to shares of Class A common stock acquired in open market transactions or pursuant to the PIPE Investment) during the lock-up period (which has expired) and were granted certain registration rights with respect to their respective shares of our common stock, in each case, on the terms and subject to the conditions therein.

In particular, the Registration Rights Agreement provides for the following registration rights:

- *Registration rights*. Promptly, but in any event within 45 days following the Closing Date, Hyperfine is required to use its commercially reasonable efforts to file a registration statement under the Securities Act to permit the public resale of all registrable securities as permitted by Rule 415 of the Securities Act and to cause

such registration statement to be declared effective as soon as practicable after the filing thereof, but in no event later than 45 days following the filing deadline (or 60 days following the filing deadline if the registration statement is reviewed by and receives comments from the SEC). As soon as practicable following the date of effectiveness of the registration statement, but in any event within two business days of such date, Hyperfine will notify the holders of registrable securities of the effectiveness of such registration statement. The registration statement was initially filed on January 24, 2022 and initially declared effective by the SEC on February 1, 2022. The post-effective amendment to the registration statement filed on January 24, 2023 was declared effective by the SEC on January 30, 2023. At any time at which Hyperfine has an effective shelf registration statement with respect to a holder's registrable securities, any such holder may request to sell all or a portion of their registrable securities pursuant to an underwritten offering pursuant to such shelf registration statement, provided that such holder(s) reasonably expect any such sales to generate aggregate gross proceeds in excess of $25 million or reasonably expect to sell all of the registrable securities held by such holder, but in no event for aggregate gross proceeds of less than $5 million in gross proceeds. Hyperfine will enter into an underwriting agreement with a managing underwriter or underwriters selected by the initiating holder(s), after consultation with Hyperfine, and will take all such other reasonable actions as are requested by the managing underwriter to expedite or facilitate the disposition of such registrable securities.

- *Demand registration rights*. At any time after the Closing Date, if Hyperfine does not have an effective registration statement outstanding, Hyperfine will be required, upon the written request of the holders of at least a majority-in-interest of the then-outstanding registrable securities held by the Sponsor Group Holders or the Legacy Hyperfine Holders, as soon as practicable but not more than 45 days after receipt of such written request, to file a registration statement and to effect the registration of all or part of their registrable securities. Hyperfine is not obligated to effect more than an aggregate of (i) one demand registration at the request of one or more Sponsor Group Holders or (ii) an aggregate of three registrations pursuant to a demand registration request.

- *Piggyback registration rights*. At any time after the Closing Date, if Hyperfine proposes to file a registration statement under the Securities Act to register any of its equity securities, or securities or other obligations exchangeable or convertible into equity securities, or to conduct a public offering, either for its own account or for the account of any other person, subject to certain exceptions and reductions as described in the Registration Rights Agreement, then Hyperfine will give written notice of such proposed filing to the holders of registrable securities as soon as practicable but not less than 10 days before the anticipated filing of such registration statement. Upon the written request of any holder of registrable securities in response to such written notice, Hyperfine will, in good faith, cause such registrable securities to be included in the registration statement and use its commercially reasonable efforts to cause the underwriters of any proposed underwritten offering to include such holders' registrable securities on the same terms and conditions as any similar securities of Hyperfine included in such registration.

Transfer Agent and Registrar

The transfer agent for our capital stock is Continental Stock Transfer & Trust Company.

Stock Exchange Listing

Hyperfine's Class A common stock is listed for trading on The Nasdaq Stock Market under the symbol "HYPR."

HYPERFINE, INC.
Stock Option Grant Notice

Name: Brett Hale

Grant Number:

Grant Date: 13-Feb-2023

Grant Type: Non-Qualified Stock Option

Grant Shares: 1,000,000

Exercise Price: $1.23 USD

Expiration Date: 13-Feb-2033

Vesting Schedule: This Option shall become exercisable (and the Shares issued upon exercise shall be vested) as follows provided the Participant is an Employee of the Company or of an Affiliate on the applicable vesting date:

25% at the mid-point of the calendar quarter that includes the one year anniversary of the Grant Date, and 2.083% at the end of each month thereafter.

The foregoing rights are cumulative and are subject to the other terms and conditions of this Agreement.

The Company and the Participant acknowledge receipt of this Stock Option Grant Notice and agree to the terms of the Stock Option Agreement attached hereto, and the terms of this Option Grant as set forth above.

HYPERFINE, INC.

By:/s/ Maria Sainz
Name: Maria Sainz
Title: President and CEO

/s/ Brett Hale
Participant: Brett Hale

HYPERFINE, INC.

NON-QUALIFIED STOCK OPTION AGREEMENT

AGREEMENT made as of the date of grant set forth in the Stock Option Grant Notice by and between Hyperfine, Inc. (the "Company"), a Delaware corporation, and the individual whose name appears on the Stock Option Grant Notice (the "Participant").

WHEREAS, the Company desires to grant to the Participant an Option to purchase shares of its Class A common stock, $0.0001 par value per share (the "Shares") as an inducement material to the Participant's entering into employment as Chief Financial Officer and Chief Administrative Officer of the Company, in accordance with the terms of an Offer Letter with the Company dated February 2, 2023; and

WHEREAS, the Company and the Participant each intend that the Option granted herein shall be a non-qualified stock option.

NOW, THEREFORE, in consideration of the mutual covenants hereinafter set forth and for other good and valuable consideration, the parties hereto agree as follows:

1. DEFINITIONS.

Unless otherwise specified or unless the context otherwise requires, the following terms, as used in this Agreement, have the following meanings:

Administrator means the Board of Directors, unless it has delegated power to act on its behalf to the Committee, in which case the term Administrator means the Committee.

Affiliate means a corporation which, for purposes of Section 424 of the Code, is a parent or subsidiary of the Company, direct or indirect.

Board of Directors means the Board of Directors of the Company.

Cause means, with respect to the Participant: (a) dishonesty with respect to the Company or any Affiliate, (b) insubordination, substantial malfeasance or non-feasance of duty, (c) unauthorized disclosure of confidential information, (d) breach by a Participant of any provision of any employment, consulting, advisory, nondisclosure, non-competition or similar agreement between the Participant and the Company or any Affiliate or any material written policy of the Company or any Affiliate, and (e) conduct substantially prejudicial to the business of the Company or any Affiliate; provided, however, that any provision in an agreement between a Participant and the Company or an Affiliate, which contains a conflicting definition of Cause for termination and which is in effect at the time of such termination, shall supersede this definition. The determination of the Administrator as to the existence of Cause will be conclusive on the Participant and the Company.

Class A common stock means shares of the Company's Class A common stock, $0.0001 par value per share.

Code means the United States Internal Revenue Code of 1986, as amended, including any successor statute, regulation and guidance thereto.

Committee means the committee of the Board of Directors, if any, to which the Board of Directors has delegated power to act.

Corporate Transaction means a merger, consolidation, or sale of all or substantially all of the Company's assets or the acquisition of all of the outstanding voting stock of the Company (or similar transaction) in a single transaction or a series of related transactions by a single entity, other than a transaction to merely to change the state of incorporation or in which the Company is the surviving corporation. Where a Corporate Transaction involves a tender offer that is reasonably expected to be followed by a merger (as determined by the Administrator), the Corporate Transaction will be deemed to have occurred upon consummation of the tender offer.

Disability or Disabled means permanent and total disability as defined in Section 22(e)(3) of the Code.

Director means any member of the Board of Directors.

Employee means any employee of the Company or of an Affiliate (including, without limitation, an employee who is also serving as an officer or director of the Company or of an Affiliate).

Exchange Act means the Securities Exchange Act of 1934, as amended.

Fair Market Value of a Share of Class A common stock means:

If the Class A common stock is listed on a national securities exchange or traded in the over-the-counter market and sales prices are regularly reported for the Class A common stock, the closing or, if not applicable, the last price of the Class A common stock on the composite tape or other comparable reporting system for the trading day on the applicable date and if such applicable date is not a trading day, the last market trading day prior to such date;

If the Class A common stock is not traded on a national securities exchange but is traded on the over-the-counter market, if sales prices are not regularly reported for the Class A common stock for the trading day referred to in clause (1), and if bid and asked prices for the Class A common stock are regularly reported, the mean between the bid and the asked price for the Class A common stock at the close of trading in the over-the-counter market for the trading day on which Class A common stock was traded on the applicable date and if such applicable date is not a trading day, the last market trading day prior to such date; and

If the Class A common stock is neither listed on a national securities exchange nor traded in the over-the-counter market, such value as the Administrator, in good faith, shall determine in compliance with applicable laws.

Non-Qualified Option means a stock option which is not intended to qualify as an incentive stock option under Section 422 of the Code.

Option means a Non-Qualified Option granted as an inducement award under NASDAQ Listing Rule 5635(c)(4).

Securities Act means the United States Securities Act of 1933, as amended.

Survivor means the deceased Participant's legal representatives and/or any person or persons who acquire the Option by will or by the laws of descent and distribution.

2. GRANT OF OPTION.

The Company hereby grants to the Participant the right and option to purchase all or any part of an aggregate of the number of Shares set forth in the Stock Option Grant Notice, on the terms and conditions and subject to all the limitations set forth herein and under United States securities and tax laws.

3. EXERCISE PRICE.

The exercise price of the Shares covered by the Option shall be the amount per Share set forth in the Stock Option Grant Notice, subject to adjustment, as provided in Section 10, in the event of a stock split, reverse stock split or other events affecting the holders of Shares after the date hereof (the "Exercise Price"). Payment shall be made in accordance with Section 6 of this Agreement.

4. EXERCISABILITY OF OPTION.

Subject to the terms and conditions set forth in this Agreement, the Option granted hereby shall become vested and exercisable as set forth in the Stock Option Grant Notice and is subject to the other terms and conditions of this Agreement.

5. TERM OF OPTION.

This Option shall terminate on the Option Expiration Date as specified in the Stock Option Grant Notice, but shall be subject to earlier termination as provided herein.

If the Participant ceases to be an Employee of the Company or of an Affiliate for any reason other than the death or Disability of the Participant, or termination of the Participant for Cause (the "Termination Date"), the Option to the extent then vested and exercisable pursuant to Section 4 hereof as of the Termination Date, and not previously terminated in accordance with this Agreement, may be exercised within three months after the Termination Date, or on or prior to the Option Expiration Date as specified in the Stock Option Grant Notice, whichever is earlier, but

may not be exercised thereafter except as set forth below. In such event, the unvested portion of the Option shall not be exercisable and shall expire and be cancelled on the Termination Date.

Notwithstanding the foregoing, in the event of the Participant's Disability or death within three months after the Termination Date, the Participant or the Participant's Survivors may exercise the Option within one year after the Termination Date, but in no event after the Option Expiration Date as specified in the Stock Option Grant Notice.

In the event the Participant's service is terminated by the Company or an Affiliate for Cause, the Participant's right to exercise any unexercised portion of this Option even if vested shall cease immediately as of the time the Participant is notified such Participant's service is terminated for Cause, and this Option shall thereupon terminate. Notwithstanding anything herein to the contrary, if subsequent to the Participant's termination, but prior to the exercise of the Option, the Administrator determines that, either prior or subsequent to the Participant's termination, the Participant engaged in conduct which would constitute Cause, then the Participant shall immediately cease to have any right to exercise the Option and this Option shall thereupon terminate.

In the event of the Disability of the Participant, , the Option shall be exercisable within one year after the Participant's termination of due to Disability or, if earlier, on or prior to the Option Expiration Date as specified in the Stock Option Grant Notice. In such event, the Option shall be exercisable:

(a) to the extent that the Option has become exercisable but has not been exercised as of the date of the Participant's termination of service due to Disability; and

(b) in the event rights to exercise the Option accrue periodically, to the extent of a pro rata portion through the date of the Participant's termination of service due to Disability of any additional vesting rights that would have accrued on the next vesting date had the Participant not become Disabled. The proration shall be based upon the number of days accrued in the current vesting period prior to the date of the Participant's termination of service due to Disability.

In the event of the death of the Participant while an Employee of the Company or of an Affiliate, the Option shall be exercisable by the Participant's Survivors within one year after the date of death of the Participant or, if earlier, on or prior to the Option Expiration Date as specified in the Stock Option Grant Notice. In such event, the Option shall be exercisable:

(x) to the extent that the Option has become exercisable but has not been exercised as of the date of death; and

(y) in the event rights to exercise the Option accrue periodically, to the extent of a pro rata portion through the date of death of any additional vesting rights that would have accrued on the next vesting date had the Participant

not died. The proration shall be based upon the number of days accrued in the current vesting period prior to the Participant's date of death.

6. METHOD OF EXERCISING OPTION.

Subject to the terms and conditions of this Agreement, the Option may be exercised by written notice to the Company or its designee, in substantially the form of Exhibit A attached hereto (or in such other form acceptable to the Company, which may include electronic notice). Such notice shall state the number of Shares with respect to which the Option is being exercised and shall be signed by the person exercising the Option (which signature may be provided electronically in a form acceptable to the Company). Payment of the Exercise Price for such Shares shall be made (a) in United States dollars in cash or by check; or (b) at the discretion of the Administrator, through delivery of shares of Class A common stock held for at least six months (if required to avoid negative accounting treatment) having a Fair Market Value (as defined below) equal as of the date of the exercise to the aggregate cash exercise price for the number of Shares as to which the Option is being exercised; (c) at the discretion of the Administrator, by having the Company retain from the Shares otherwise issuable upon exercise of the Option, a number of Shares having a Fair Market Value equal as of the date of exercise to the aggregate exercise price for the number of Shares as to which the Option is being exercised; or (d) at the discretion of the Administrator, in accordance with a cashless exercise program established with a securities brokerage firm, and approved by the Administrator; or (e) at the discretion of the Administrator, by any combination of (a), (b), (c) and (d) above; or (f) at the discretion of the Administrator, by payment of such other lawful consideration as the Administrator may determine. The Company shall deliver such Shares as soon as practicable after the notice shall be received, provided, however, that the Company may delay issuance of such Shares until completion of any action or obtaining of any consent, which the Company deems necessary under any applicable law (including, without limitation, state securities or "blue sky" laws). The Shares as to which the Option shall have been so exercised shall be registered in the Company's share register in the name of the person so exercising the Option (or, if the Option shall be exercised by the Participant and if the Participant shall so request in the notice exercising the Option, shall be registered in the Company's share register in the name of the Participant and another person jointly, with right of survivorship) and shall be delivered as provided above to or upon the written order of the person exercising the Option. In the event the Option shall be exercised, pursuant to Section 5 hereof, by any person other than the Participant, such notice shall be accompanied by appropriate proof of the right of such person to exercise the Option. All Shares that shall be purchased upon the exercise of the Option as provided herein shall be fully paid and nonassessable.

7. PARTIAL EXERCISE.

Exercise of this Option to the extent above stated may be made in part at any time and from time to time within the above limits, except that no fractional share shall be issued pursuant to this Option.

8. NON-ASSIGNABILITY.

The Option shall not be transferable by the Participant otherwise than by will or by the laws of descent and distribution or pursuant to a qualified domestic relations order as defined by the Code or Title I of the Employee Retirement Income Security Act or the rules thereunder. Except as provided above in this paragraph, the Option shall be exercisable, during the Participant's lifetime, only by the Participant (or, in the event of legal incapacity or incompetency, by the Participant's guardian or representative) and shall not be assigned, pledged or hypothecated in any way (whether by operation of law or otherwise) and shall not be subject to execution, attachment or similar process. Any attempted transfer, assignment, pledge, hypothecation or other disposition of the Option or of any rights granted hereunder contrary to the provisions of this Section 8, or the levy of any attachment or similar process upon the Option shall be null and void.

9. NO RIGHTS AS STOCKHOLDER UNTIL EXERCISE.

The Participant shall have no rights as a stockholder with respect to Shares subject to this Agreement until registration of the Shares in the Company's share register in the name of the Participant. Except as is expressly provided in Section 10 of this Agreement with respect to certain changes in the capitalization of the Company, no adjustment shall be made for dividends or similar rights for which the record date is prior to the date of such registration.

10. ADJUSTMENTS.

Upon the occurrence of any of the following events, the Participant's rights with respect to the Option shall be adjusted as hereinafter provided.

(a) Changes with Respect to Shares of Common Stock. If (i) the Shares shall be subdivided or combined into a greater or smaller number of shares or if the Company shall issue any Shares as a stock dividend on its outstanding Shares, or (ii) additional shares or new or different shares or other securities of the Company or other non-cash assets are distributed with respect to such Shares, the Option and the number of Shares deliverable thereunder shall be appropriately increased or decreased proportionately, and appropriate adjustments shall be made including, in the exercise price per share, to reflect such events. The Administrator may also make adjustments of the type described in this Paragraph to take into account distributions to stockholders other than those provided for in Paragraphs 10(b) below, or any other event, if the Administrator determines that adjustments are appropriate to avoid distortion in the operation of the Option, having due regard for the requirements of Section 409A, to the extent applicable. References in this Agreement to Shares will be construed to include any stock or securities resulting from an adjustment pursuant to this Paragraph 10(a).

(b) Corporate Transactions. In the event of a Corporate Transaction, the Administrator or the board of directors of any entity assuming the obligations of the Company hereunder (the "Successor Board"), shall, as to the unexercised portion of the Option, either (i) make appropriate provision for the continuation of the Option by substituting on an equitable basis for the Shares then subject to the Option either the consideration payable with respect to the outstanding Shares in connection with the Corporate Transaction or securities of any successor or acquiring entity; or (ii) upon written notice to the Participant, provide that the Option must be exercised (to the extent then exercisable, within a specified number of days of the date of such notice, at the end of which period the Option shall terminate); or (iii) terminate the Option in exchange for payment of an

amount equal to the consideration payable upon consummation of such Corporate Transaction to the holder of the number of Shares into which the Option would have been exercisable (either (A) to the extent then exercisable or, (B) at the discretion of the Administrator, any such Options being made partially or fully exercisable for purposes of this Subclause) less the aggregate exercise price thereof. For purposes of determining the payments to be made pursuant to Subclause (iii) above, in the case of a Corporate Transaction the consideration for which, in whole or in part, is other than cash, the consideration other than cash shall be valued at the fair value thereof as determined in good faith by the Board of Directors. For the avoidance of doubt, if the per share exercise price of the Option or portion thereof is equal to or greater than the Fair Market Value of one Share of Class A common stock, such Option may be cancelled with no payment due hereunder or otherwise in respect thereof. Except as the Administrator may otherwise determine, the Option will automatically terminate immediately upon the consummation of a Corporate Transaction,

(c) Recapitalization or Reorganization. In the event of a recapitalization or reorganization of the Company other than a Corporate Transaction pursuant to which securities of the Company or of another corporation are issued with respect to the outstanding Shares, the Participant upon exercising the Option after the recapitalization or reorganization shall be entitled to receive for the price paid upon such exercise or acceptance if any, the number of replacement securities which would have been received if the Option had been exercised prior to such recapitalization or reorganization.

(d) Modification of Options. Notwithstanding the foregoing, any adjustments made pursuant to Subsection (a), (b) or (c) above shall be made only after the Administrator determines whether such adjustments would cause any adverse tax consequences, including, but not limited to, pursuant to Section 409A of the Code. If the Administrator determines that such adjustments would constitute a modification of the Option or other adverse tax consequence to the Participant, it may refrain from making such adjustments, unless the Participant specifically agrees in writing that such adjustment be made.

(e). Dissolution or Liquidation of the Company. Upon the dissolution or liquidation of the Company, the Option will terminate and become null and void; provided, however, that if the rights of the Participant or the Participant's Survivors have not otherwise terminated and expired, the Participant or the Participant's Survivors will have the right immediately prior to such dissolution or liquidation to exercise the Option to the extent that the Option is exercisable as of the date immediately prior to such dissolution or liquidation.

11. TAXES.

The Participant acknowledges and agrees that (i) any income or other taxes due from the Participant with respect to this Option or the Shares issuable pursuant to this Option shall be the Participant's responsibility; (ii) the Participant was free to use professional advisors of such Participant's choice in connection with this Agreement, has received advice from such Participant's professional advisors in connection with this Agreement, understands its meaning and import, and is entering into this Agreement freely and without coercion or duress; (iii) the Participant has not received and is not relying upon any advice, representations or assurances made by or on behalf of the Company or any Affiliate or any employee of or counsel to the Company or any Affiliate regarding any tax or other effects or implications of the Option, the Shares or other

matters contemplated by this Agreement; and (iv) neither the Administrator, the Company, its Affiliates, nor any of its officers or directors, shall be held liable for any applicable costs, taxes, or penalties associated with the Option if, in fact, the Internal Revenue Service were to determine that the Option constitutes deferred compensation under Section 409A of the Code.

The Participant agrees that the Company may withhold from the Participant's remuneration, if any, the minimum statutory amount of federal, state and local withholding taxes attributable to such amount that is considered compensation includable in such person's gross income. At the Company's discretion, the amount required to be withheld may be withheld in cash from such remuneration, or in kind from the Shares otherwise deliverable to the Participant on exercise of the Option. The Participant further agrees that, if the Company does not withhold an amount from the Participant's remuneration sufficient to satisfy the Company's income tax withholding obligation, the Participant will reimburse the Company on demand, in cash, for the amount under-withheld.

12. PURCHASE FOR INVESTMENT.

Unless the offering and sale of the Shares to be issued upon the particular exercise of the Option shall have been effectively registered under the Securities Act, the Company shall be under no obligation to issue the Shares covered by such exercise unless the Company has determined that such exercise and issuance would be exempt from the registration requirements of the Securities Act and until the following conditions have been fulfilled:

(a) The person(s) who exercise the Option shall warrant to the Company, at the time of such exercise, that such person(s) are acquiring such Shares for their own respective accounts, for investment, and not with a view to, or for sale in connection with, the distribution of any such Shares, in which event the person(s) acquiring such Shares shall be bound by the provisions of the following legend which shall be endorsed upon any certificate(s) evidencing the Shares issued pursuant to such exercise:

> "The shares represented by this certificate have been taken for investment and they may not be sold or otherwise transferred by any person, including a pledgee, unless (1) either (a) a Registration Statement with respect to such shares shall be effective under the Securities Act of 1933, as amended, or (b) the Company shall have received an opinion of counsel satisfactory to it that an exemption from registration under such Act is then available, and (2) there shall have been compliance with all applicable state securities laws;" and

(b) If the Company so requires, the Company shall have received an opinion of its counsel that the Shares may be issued upon such particular exercise in compliance with the Securities Act without registration thereunder. Without limiting the generality of the foregoing, the Company may delay issuance of the Shares until completion of any action or obtaining of any consent, which the Company deems necessary or advisable (including without limitation state securities or "blue sky" laws).

13. RESTRICTIONS ON TRANSFER OF SHARES.

13.1 The Participant agrees that in the event the Company proposes to offer for sale to the public any of its equity securities and such Participant is requested by the Company and any underwriter engaged by the Company in connection with such offering to sign an agreement restricting the sale or other transfer of Shares, then it will promptly sign such agreement and will not transfer, whether in privately negotiated transactions or to the public in open market transactions or otherwise, any Shares or other securities of the Company held by the Participant during such period as is determined by the Company and the underwriters, not to exceed 180 days following the closing of the offering, plus such additional period of time as may be required to comply with FINRA rules or similar rules thereto promulgated by another regulatory authority (such period, the "Lock-Up Period"). Such agreement shall be in writing and in form and substance reasonably satisfactory to the Company and such underwriter and pursuant to customary and prevailing terms and conditions. Whether or not the Participant has signed such an agreement, the Company may impose stop-transfer instructions with respect to the Shares or other securities of the Company subject to the foregoing restrictions until the end of the Lock-Up Period.

13.2 The Participant acknowledges and agrees that neither the Company, its stockholders nor its directors and officers, has any duty or obligation to disclose to the Participant any material information regarding the business of the Company or affecting the value of the Shares before, at the time of, or following a termination of the service of the Participant by the Company, including, without limitation, any information concerning plans for the Company to make a public offering of its securities or to be acquired by or merged with or into another firm or entity.

14. NO OBLIGATION TO MAINTAIN RELATIONSHIP.

The Participant acknowledges that: (i) the Company is not by this Agreement obligated to continue the Participant as an employee of the Company or an Affiliate; (ii) the grant of the Option is a one-time benefit which does not create any contractual or other right to receive future grants of options, or benefits in lieu of options; (iii) all determinations with respect to any such future grants, including, but not limited to, the times when options shall be granted, the number of shares subject to each option, the option price, and the time or times when each option shall be exercisable, will be at the sole discretion of the Company; (iv) the value of the Option is an extraordinary item of compensation which is outside the scope of the Participant's employment or consulting contract, if any; and (v) the Option is not part of normal or expected compensation for purposes of calculating any severance, resignation, redundancy, end of service payments, bonuses, long-service awards, pension or retirement benefits or similar payments.

15. CLAWBACK

Notwithstanding anything to the contrary contained in this Agreement, the Company may recover from the Participant any compensation received from this Option or cause the Participant to forfeit the Option (whether or not vested) in the event that the Company's Clawback Policy as then in effect is triggered.

16. NOTICES.

Any notices required or permitted by the terms of this Agreement shall be given by recognized courier service, facsimile, registered or certified mail, return receipt requested, addressed as follows:

If to the Company:

Hyperfine, Inc.
351 New Whitfield Street
Guilford, Connecticut 06437
Attention: Chief Executive Officer

If to the Participant at the Participant's most recent address as shown in the employment or stock records of the Company.

Any such notice shall be deemed to have been given upon the earlier of receipt, one business day following delivery to a recognized courier service or three business days following mailing by registered or certified mail.

17. GOVERNING LAW.

This Agreement shall be governed by and construed in accordance with the laws of the State of Delaware, without giving effect to the conflict of law principles thereof. For the purpose of litigating any dispute that arises under this Agreement, the parties hereby consent to exclusive jurisdiction in Connecticut and agree that such litigation shall be conducted in the state courts of Connecticut or the federal courts of the United States for the State of Connecticut**.**

18. BENEFIT OF AGREEMENT.

Subject to the provisions hereof, this Agreement shall be for the benefit of and shall be binding upon the heirs, executors, administrators, successors and assigns of the parties hereto.

19. ENTIRE AGREEMENT.

This Agreement embodies the entire agreement and understanding between the parties hereto with respect to the subject matter hereof and supersedes all prior oral or written agreements and understandings relating to the subject matter hereof (with the exception of acceleration of vesting provisions contained in any other agreement with the Company). No statement,

representation, warranty, covenant or agreement not expressly set forth in this Agreement shall affect or be used to interpret, change or restrict the express terms and provisions of this Agreement.

20. MODIFICATIONS AND AMENDMENTS.

The terms and provisions of this Agreement may be modified or amended by the Administrator; provided, however, the Administrator not take any action that is considered a direct or indirect "repricing" for purposes of the stockholder approval rules of the applicable securities exchange or inter-dealer quotation system on which the Shares are listed, including any other action that is treated as a repricing under generally accepted accounting principles. Any modification or amendment of this Agreement shall not, without the consent of the Participant, adversely affect the Participant's rights under this Agreement.

21. WAIVERS AND CONSENTS.

The terms and provisions of this Agreement may be waived, or consent for the departure therefrom granted, only by written document executed by the party entitled to the benefits of such terms or provisions. No such waiver or consent shall be deemed to be or shall constitute a waiver or consent with respect to any other terms or provisions of this Agreement, whether or not similar. Each such waiver or consent shall be effective only in the specific instance and for the purpose for which it was given, and shall not constitute a continuing waiver or consent.

22. DATA PRIVACY.

By entering into this Agreement, the Participant: (i) authorizes the Company and each Affiliate, and any agent of the Company or any Affiliate facilitating the grant of options under this Agreement, to disclose to the Company or any of its Affiliates such information and data as the Company or any such Affiliate shall request in order to facilitate the grant of options; (ii) to the extent permitted by applicable law waives any data privacy rights the Participant may have with respect to such information, and (iii) authorizes the Company and each Affiliate to store and transmit such information in electronic form for the purposes set forth in this Agreement.

Exhibit A

NOTICE OF EXERCISE OF STOCK OPTION

To: Hyperfine, Inc.

IMPORTANT NOTICE: This form of Notice of Exercise may only be used at such time as the Company has filed a Registration Statement with the Securities and Exchange Commission under which the issuance of the Shares for which this exercise is being made is registered and such Registration Statement remains effective.

Ladies and Gentlemen:

I hereby exercise my Stock Option to purchase _____ shares (the "Shares") of the Class A common stock, $0.0001 par value, of Hyperfine, Inc. (the "Company"), at the exercise price of $_____ per share, pursuant to and subject to the terms of that Stock Option Grant Notice dated _____, 20__.

I understand the nature of the investment I am making and the financial risks thereof. I am aware that it is my responsibility to have consulted with competent tax and legal advisors about the relevant national, state and local income tax and securities laws affecting the exercise of the Option and the purchase and subsequent sale of the Shares.

I am paying the option exercise price for the Shares as follows:

_____

Please issue the Shares (check one):

☐ to me; or

☐ to me and _____, as joint tenants with right of survivorship,

at the following address:

_____

_____

_____

My mailing address for stockholder communications, if different from the address listed above, is:

_____

_____

_____

Very truly yours,

_____

Participant (signature)

_____

Print Name

_____

Date

Exhibit A-2

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement No. 333-263897 on Form S-8 and Registration Statement No. 333-262300 on Form S-3 of our report dated March 22, 2023, relating to the combined and consolidated financial statements of Hyperfine, Inc., appearing in this Annual Report on Form 10-K for the year ended December 31, 2022.

/s/ Deloitte & Touche LLP
New York, New York
March 22, 2023

Exhibit 31.1

CERTIFICATIONS UNDER SECTION 302

I, Maria Sainz, certify that:

1. I have reviewed this annual report on Form 10-K of Hyperfine, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 22, 2023

/s/ Maria Sainz

Maria Sainz
President and Chief Executive Officer
(principal executive officer)

Exhibit 31.2

CERTIFICATIONS UNDER SECTION 302

I, Alok Gupta, certify that:

1. I have reviewed this annual report on Form 10-K of Hyperfine, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 22, 2023

/s/ Alok Gupta

Alok Gupta
Chief Financial Officer
(principal financial officer)

Exhibit 32

CERTIFICATIONS UNDER SECTION 906

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), each of the undersigned officers of Hyperfine, Inc., a Delaware corporation (the "Company"), does hereby certify, to such officer's knowledge, that:

The Annual Report for the year ended December 31, 2022 (the "Form 10-K") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 22, 2023

/s/ Maria Sainz

Maria Sainz
President and Chief Executive Officer
(principal executive officer)

Dated: March 22, 2023

/s/ Alok Gupta

Alok Gupta
Chief Financial Officer
(principal financial officer)