Risk Factors Comparison 2025-03-17 to 2024-03-22 Form: 10-K

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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 Class A 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 health 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 health 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 $ **40. 7 million and $** 44 ~~. 2 million and $ 73~~ . 2 million for the years ended December 31, **2024 and** 2023 ~~and 2022~~ , respectively. As of December 31, ~~2023~~ **2024** , we had an accumulated deficit of $ ~~253~~ **294** . ~~7~~ **4** 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 **commercialization of our products and** continuing ~~development and commercialization of our products and research and~~ development efforts for **improved and** 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. In addition, as a public company, we will continue to incur significant legal, accounting, administrative, insurance and other expenses. 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 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, develop clinical evidence, 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. ~~SEC regulations limit the funds we can raise during 12 months under our shelf registration statement on Form S- 3. In November 2023, we filed a shelf registration statement on Form S- 3 with the SEC pursuant to which we registered for sale up to $ 150 million of any combination of our Class A common stock, preferred stock, debt securities, warrants, rights and / or~~

~~units from time to time and at prices and on terms that we may determine. Our shelf registration statement on Form S- 3 also included a prospectus covering up to an aggregate of $ 50. 0 million in shares of Class A common stock that we may issue and sell from time to time, through B. Riley acting as our sales agent, pursuant to the Sales Agreement for our " at- the- market " equity program. There can be no assurance that B. Riley will be successful in consummating future sales based on prevailing market conditions or in the quantities or at the prices that we deem appropriate. In addition, under current SEC regulations, as of the filing of this Annual Report on Form 10- K, our public float is less than $ 75 million, and under SEC regulations for so long as our public float remains less than $ 75 million, the amount we can raise through primary public offerings of securities in any twelve- month period using shelf registration statements is limited to an aggregate of one- third of our public float, which is referred to as the baby shelf rules. As of March 5, 2024, our public float was approximately $ 68. 5 million, based on 54, 760, 324 shares of outstanding common stock held by non- affiliates and at a price of $ 1. 25 per share, which was the last reported sale price of our common stock on the Nasdaq Capital Market on March 5, 2024. As a result of our public float being below $ 75 million, we will be limited by the baby shelf rules until such time our public float exceeds $ 75 million, which means we only have the capacity to sell shares up to one- third of our public float in primary offerings under our shelf registration statement on Form S- 3 in any twelve- month period.~~ 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; • the budgets, budget cycles and approval processes of our customers and potential customers and any changes affecting such budgets, budget cycles and approval processes; • pricing actions, such as ~~the~~ pricing adjustments we ~~made~~ **make** to our business model ~~during the first quarters of 2022 and 2023 in which we increased the price of the device while lowering the price of the service and support annual charges~~ ; • 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 political instability and military conflict, such as the conflicts in Ukraine and the Middle East, 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, 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. 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 United States ~~,~~ 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 ~~,~~ **and** 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. Health technology development is costly and involves continual technological change, which may render our current or future products obsolete. The market for point- of- care health technology and 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, develop or acquire and market new technologies and to continue to improve our technology, products and services to meet customer needs. A failure to adequately develop or acquire technology that will address customer requirements adequately, or to introduce such improved products and services 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 products and services at competitive prices. Technological advances by one or more competitors or future entrants into the field may result in our current products and services 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, 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 customers or add new customers. If we do not successfully continue our sales efforts and promotional activities, particularly to health systems and large institutions, or if existing customers 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 increasing and maintaining the volume of use of our products by our customers. 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, and service and support agreements for use of device hardware and services, there is risk that any decline in sales, service and support 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. **In addition, we expect that changing policies of and actions by the U. S. government will adversely affect the ability of certain of our current, or potential, customers or collaborators to purchase, maintain or retain our products and services. In particular, upon taking office in January 2025, the Trump administration effectively prevented the NIH from reviewing and awarding grants, or paying out funds under already awarded grants, including for research or other projects that involve our products and services. If this hold on government grants continues, or if the U. S. government takes any other actions to limit funds available for life science or healthcare research or other projects, we expect that it will affect certain of our current, or potential, customers and may have a material and adverse impact on our revenue, business, financial condition and results of operations.** We expect to generate ~~an increasing~~ **a substantial** 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 ~~40~~ **51** % of total revenue for the year ended December 31, ~~2023~~ **2024** . We believe that a substantial percentage of our future revenue will come from international sources as we continue to commercialize our products and services, having received marketing authorization for brain imaging in several countries, including the European Union (CE **Mark**), the United Kingdom (UKCA **Mark**), Canada, Australia and New Zealand ~~, and as we~~ **. We expect to continue to** 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 conflicts in Ukraine and the Middle East, 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 the Middle East 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 the conflict in Ukraine 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. **Additionally, the imposition of substantial tariffs by the United States on imports from various countries, including China, Canada, and Mexico, and the possible countermeasures by these countries could increase costs, disrupt the global supply chain, and create additional operational challenges. The uncertainty surrounding future trade relationships and the potential for increased market volatility and currency exchange rate fluctuations along with tariffs and trade regulations could have an adverse effect on our business.** 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 have undertaken internal restructuring activities that could result in disruptions to our business or otherwise materially harm our results of operations or financial condition. ~~In December~~ **On January 28,** ~~2022~~ **2025** , we **implemented** ~~announced that we committed to~~ an organizational restructuring designed to decrease our costs and create a more streamlined organization to support our business **priorities** . As a result, we terminated approximately ~~13~~ **14** % of our global workforce **. The restructuring affects** ~~including, among others, the~~ employees ~~of our subsidiary, Liminal. We believe this re~~ **predominantly in technical positions and is largely focused on internally** - **facing roles** ~~prioritized strategic focus was~~ - **as we evolve from** ~~the best way to optimize our financial and other resources to advance our goal of developing~~ **development** ~~and~~ **stage to** ~~commercializing~~ ----- **commercial stage** ~~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 have initially expected. 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 the Founder of Legacy Hyperfine and Liminal and our director, Dr. Jonathan Rothberg, our 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 health technology and 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. 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 primarily 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. We have experienced and may continue to experience pricing pressures from contract suppliers or manufacturers on which we rely. 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 business model, through the sale of device and service and support agreements which is still relatively new in the healthcare industry. If companies do not adopt to this business model and our device does not achieve widespread adoption, or if there is a reduction in demand for the purchase of our device and service and support agreements, our business, financial condition, and results of operations could be adversely affected. **In addition, reduction in Medicaid or other healthcare reimbursements may impact our domestic customers which may eventually have an adverse impact on us. Other actions which have not yet been announced create uncertainty and are difficult to predict and or manage.** 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. **The** ~~Quality~~ **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 solutions or to achieve adequate clinical feasibility, 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 the software that comes with the service and support agreement to be 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 or decide that a traditional MRI system is sufficient to meet their needs. 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~~ **Rothberg family** . A TSEA by and among Butterfly Network, Inc., ~~AI~~ **OrphAI** Therapeutics ~~, Inc., Quantum- Si Incorporated, 4Bionics LLC, identifeye Health~~ Inc. (f / k / a ~~Tesseract~~ **AI Therapeutics, Inc.), Quantum- Si Incorporated, 4Bionics LLC, identifeye** Health ~~, Inc.), Detect,~~ 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 LLC, 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~~ **OrphAI** Therapeutics ~~,~~ Inc., identifeye Health Inc. and Detect, Inc. was signed in July 2021 and became effective upon the closing of our December 2021 business combination. 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 received marketing authorization for brain imaging in several countries, including the European

Union (CE **Mark**), the United Kingdom (UKCA **Mark**), Canada, Australia and New Zealand. 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~~ **difficulties** in staffing and managing our international operations; • ~~Multiple~~ **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~~ **reduced** or varied protection for intellectual property rights in some countries; • ~~Obtaining~~ **obtaining** regulatory clearance where required for our products in various countries; • ~~Requirements~~ **requirements** to maintain data and the processing of that data on servers located within such countries; • ~~Limits~~ **limits** on our ability to penetrate international markets if we are required to manufacture our products locally; • ~~Financial~~ **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~~ **restrictions** on the site- of- service for use of our products and the economics related thereto for physicians and other healthcare practitioners; • ~~Natural~~ **natural** disasters and economic instability, including outbreak of disease, boycotts, curtailment of trade and other market restrictions; • ~~Wars~~ **wars** , terrorism and political unrest, such as the conflicts in Ukraine and the Middle East, 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~~ **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. 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 **, tariffs** and overall economic conditions and uncertainties. For instance, if inflation **, tariffs** 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~~ **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. 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~~ **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, ~~2023~~ **2024** , we had federal net operating loss carryforwards (" NOLs ") to offset future taxable income of approximately $ ~~170~~ **195. 1** million, of which $ 12. 1 million will begin to expire in 2034 if not utilized. As of December 31, ~~2023~~ **2024** , Liminal had federal NOLs to offset future taxable income of approximately $ ~~14~~ **15** . ~~7~~ **6** 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 our December 2021 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 portable MRI system in 2020. In February and October 2023, ~~we~~ **the Company** received ~~additional~~ 510 (k) clearances from the FDA **for its** ~~of the latest updates to our~~ Swoop ® system AI- powered software. The combination of these two software updates ~~significantly improved diffusion- weighted imaging (" DWI ")~~ , incorporated deep- learning based denoising in the post- processing of ~~DWI~~ images for crisper images, and improved image quality for all Swoop ® system sequences. ~~The~~ **In July 2024, we received 510 (k) clearance from the FDA of the ninth- generation AI- powered Swoop ® system software. This latest software update released to date significantly reduces scan times across multiple MR sequences without sacrificing image quality. Outside of the United States, the** Swoop ® system has received marketing authorization for brain imaging in several countries, including the European Union (CE **Mark**), the United Kingdom **(UKCA Mark)** , Canada, Australia and New Zealand **. In October 2024 and February 2025, the Company received CE Mark and UKCA Mark approval for the latest generation of software** . All of our revenue to date has been generated from sales of the Swoop ® system and related services. 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 our commercially marketed devices. 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. **More broadly, future legislation or regulation may materially impact the ability of the FDA, and other regulatory agencies with jurisdiction over medical products or services, to operate as they have historically operated.** 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 **. Disruptions at the FDA, the SEC and other government agencies caused by funding shortages, mass layoffs, or global health concerns could hinder their ability to hire and retain key leadership and other personnel, prevent our products from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business relies, which could negatively impact our business. The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for products to be reviewed and / or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the United States government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities during that period. In early 2025, following the inauguration of President Trump, the Trump Administration began terminating federal government employees, including at the FDA. The impact of mass layoffs at the agency and other governmental offices with which we interact is unclear at this time. However, it is expected that with a proposed reduction in staff of up to 50 %, the FDA in the future may be unlikely to meet its application review goals or to continue to be available for timely interactions with medical product developers. It is currently unclear how the U. S. medical device industry will be affected by the Trump Administration' s major changes to the FDA and the federal government as a whole. Separately, during the COVID- 19 pandemic, the FDA postponed most inspections of domestic and foreign manufacturing facilities at various points. Even though the FDA has since resumed standard inspection operations of domestic facilities where feasible, the agency has continued to monitor and implement changes to its inspectional activities to ensure the safety of its employees and those of the firms it regulates, and any resurgence of the virus or emergence of new infectious disease outbreaks may lead to future inspectional delays. Regulatory authorities outside the United States may adopt similar policy measures in response to emerging infectious disease outbreaks, epidemics, or pandemics. If a prolonged government shutdown or slowdown occurs, or if global health concerns similar to COVID- 19 prevent the FDA or other regulatory agencies from conducting their regular inspections, review, or other regulatory activities, it could significantly affect the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations** . 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 **or approval** 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, **plus** Iceland, Liechtenstein and Norway. In 2023, our Swoop ® system received **approval in the European Union (** CE ~~certification~~ **Mark). In October 2024, our latest generation of AI- powered Swoop ® system software received CE approval under the European Medical Device Regulation (MDR, EU No. 2017 / 745)** . The Medical Device Regulation became fully effective on May 26, 2021. 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. **These new requirements may have an effect on the way we design and manufacture product and products candidates and conduct our business in the EEA. For example, as a result of the continuing transition towards the Medical Device Regulation, Notified Body review times have lengthened, and product introductions or modifications could be delayed or canceled, which could adversely affect our ability to grow our business.** 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 **. We rely on contract manufacturers and component suppliers to provide the specific components and manufacturing services necessary to produce our finished medical devices and any future product candidates. This reliance also results in our reduced control over the manufacture of our devices and the protection of our trade secrets and know- how from misappropriation or inadvertent disclosure, which may adversely affect our future business prospects. Nevertheless, as the developer of the devices, we continue to have regulatory obligations to maintain oversight of our contract manufacturers to ensure compliance with, among other things, contractual obligations, specifications, and applicable quality system requirements** . 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~~ **by** us or our third- party manufacturers ~~and~~ **or** 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. **In complying with the applicable medical device regulations of the FDA and other comparable foreign regulatory authorities, we and our contact manufacturers, and any components suppliers to which such regulations apply, must spend significant time, money and effort in the areas of design and development, testing, production, record- keeping and quality control to assure that the products meet applicable specifications and regulatory requirements. Although our agreements with our contract manufacturers and component suppliers require them to perform according to applicable regulatory requirements, such as those relating to quality system controls, we cannot control the conduct of our contract manufacturers or component suppliers to implement and maintain these standards. If our contract manufacturers or component suppliers do not successfully carry out their contractual duties, meet expected deadlines or manufacture our devices in accordance with regulatory requirements, if there are disagreements between us and such parties, or if such parties are unable to support the commercialization of any of our devices for which we have or may obtain marketing authorization, we may not be able to produce, or may be delayed in producing devices sufficient to meet our supply requirements. Any delays in obtaining adequate supplies on adequate terms with respect to our devices, due to manufacturing issues, global trade policies, or for other reasons, could make it more difficult and costly to obtain marketing authorization for new products, or to produce, market and distribute our existing, authorized products.** 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 **risk to health associated with the device or 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~~ **Court** decisions **in the United States** 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, **artificial intelligence,** 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 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. 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, ~~personally~~ -- **personal data** ~~identifiable information~~ of individuals, and intellectual property and proprietary business information owned or controlled by us, our customers and other third parties. 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. We have implemented multiple layers of security measures to protect the confidentiality, integrity and availability of data and the systems and devices that store and transmit data. We utilize current security technologies, including encryption and data depersonalization, and our defenses are monitored and routinely tested. 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. 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. **Geopolitical tensions or conflicts, and the increased adoption of AI technologies, may further heighten the risk of cyber- attacks. Additionally, leveraging AI capabilities to potentially improve internal functions and operations presents further risks and challenges, including the possibility of creating new attack methods for adversaries. The use of AI to support business operations carries inherent risks related to data privacy, intellectual property, and security, such as intended, unintended, or inadvertent transmission of proprietary, confidential, or sensitive information, as well as challenges related to implementing and maintaining AI tools, such as developing and maintaining appropriate datasets for such support. If we fail to implement adequate safeguards, the use of AI may introduce additional operational vulnerabilities by producing inaccurate outcomes based on flaws in the underlying data or methodologies, or unintended results.** 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 the loss, misappropriation, corruption or unauthorized access of data, enforcement actions by U. S. states, the U. S. federal government or foreign governments, liability or sanctions under data privacy laws that protect ~~personally~~ -- **personal data** ~~identifiable information~~, regulatory penalties, litigation, including potential class action litigation ~~,~~, the incurrence of significant remediation costs,

increases to insurance premiums, disruptions to our development programs, business operations and collaborations, diversion of management efforts and damage to us and our brands' reputation, any of which could harm or have an adverse effect on our financial position and results of 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 individuals, including our customers, and patient data and employee 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 EEA residents. The GDPR, and its equivalents in the United Kingdom and Switzerland, are wide- ranging in scope, impose 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 EEA 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 strive to comply with the GDPR and its UK and Swiss equivalents, as applicable, 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 **, information systems,** or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our products could be delayed. There can be no assurance that we will not be **impacted** ~~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 customers. 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. In addition to risks affecting our own systems, we could also be negatively impacted by a security breach impacting a third party' s network and affecting us, such as our third- party vendors and service providers. In the event that these third parties do not adequately safeguard our data, cybersecurity incidents could result and negatively impact our business, operations, and financial results. 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. **In** ~~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, **there have been and continue to be a number of legislative initiatives to contain healthcare costs. Federal and state lawmakers regularly propose and, at times, enact legislation that would result in significant changes to the healthcare system, some of which are intended to contain or reduce the costs of medical products and services. Future legislative and regulatory proposals to further reform healthcare or reduce healthcare costs may prevent, limit or delay regulatory authorization of our product candidates or even lower reimbursement for the procedures associated with the use of our approved device products. More broadly, such future legislation or regulation may materially impact the ability of the FDA and other regulatory agencies to operate** as ~~well as state- level~~ **they have historically operated. The cost containment measures that payors and providers are instituting and the effect of any** healthcare reform ~~proposals,~~ **initiative implemented in the future** could ~~reduce medical procedure volumes and~~ impact **our revenue from** the **sale of our** ~~demand for medical device~~ products ~~or the prices at which we can sell products. The impact of healthcare reform legislation,~~ and ~~practices~~ **services. Coverage and reimbursement by third- party payors,** including ~~price regulation, competitive pricing, comparative effectiveness of therapies, technology assessments, and~~ managed care ~~arrangements are~~ **organizations, other private health insurers and government healthcare programs, such as Medicare and Medicaid, for our products can be limited and** uncertain. **If third- party payors do not provide coverage and adequate reimbursement for our products and services, our potential for growth and our ability to collect revenue for these products and services could be limited and our results of operations may be materially and adversely affected. Additionally,** ~~There~~ **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~~ **We cannot be sure whether additional legislative changes will be enacted, or whether any of the FDA' s regulations, guidance**

or interpretations will be changed, or what the impact of such changes on the agency and its scientific review staff, if any, may be. Furthermore, 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~~ **the pricing or profitability** of **healthcare products in** ~~various judicial and Congressional challenges to~~ certain ~~aspects of~~ **foreign jurisdictions is subject to government controls and** ~~the~~ **other measures that** ~~ACA, certain sections of the ACA~~ have ~~not~~ been ~~fully implemented or were effectively repealed~~ **prepared by legislators** ~~. 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 **government officials. While we cannot predict whether** ~~regulatory changes under the ACA remain possible, but it is unknown what form~~ any such ~~changes~~ **legislative** or **regulatory proposals or reforms will be adopted, the adoption of** any ~~law~~ **such proposals or reforms** ~~would~~ **could adversely** ~~take, and how or whether it may~~ affect the **commercial viability of our existing and potential products. In December 2022, the U. S. Congress enacted the Consolidated Appropriations Act for 2023, an omnibus appropriations bill, which included amendments to the FDCA under the Food and Drug Omnibus Reform Act of 2022 (" FDORA "). In addition to the requirement that sponsors of pivotal trials submit diversity action plans for pivotal trials (as described in " Item 1. Business- Government Regulation "), FDORA included new requirements for cyber devices, defined as any** medical device **that is** ~~industry as a whole or our~~ **or includes software that is validated** ~~business in the future. In addition to the ACA~~ , **installed, or authorized by** ~~there~~ -- **the** ~~have been~~ **manufacturer; can connect to the internet;** and **may be vulnerable to cybersecurity threats. Under the FDORA amendments to the FDCA, any application for marketing authorization of the cyber device must include a software bill of materials and a cybersecurity plan describing the methods by which the manufacturer** will **monitor** ~~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~~ , **identify** ~~to the extent that future changes affect how our products~~ and ~~services are paid for and reimbursed~~ **address cybersecurity vulnerabilities. Any failure** by **a cyber device manufacturer to** ~~government and private payers, our business could be adversely impacted. Moreover, complying~~ --- **comply** with **applicable cybersecurity requirements is considered** ~~any new legislation or reversing changes implemented under the ACA could be time- intensive and expensive, resulting in~~ a **violation of** ~~material adverse effect on~~ the ~~business~~ **FDCA and will subject the manufacturer to enforcement actions and possibly legal sanctions** . 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 **. We cannot predict what other healthcare programs and regulations will ultimately be implemented in the United States, at the federal or state level, or in foreign jurisdictions where we market our devices, nor can we predict the effects of any such future legislation or regulation on our business, financial condition and results of operations** . 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 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. 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 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 ~~If we~~ **We have in the past** ~~experience~~ **experienced** material weaknesses in our internal control over financial reporting **, and if we experience such material weaknesses in our internal control over financial reporting 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 **or cash flows** 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 **past experienced** ~~presence of maximum redemption thresholds or charter provisions common in special purpose acquisition companies (" 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 represented~~ material weaknesses in our internal controls over financial reporting **that have required us to expend substantial time and effort to remediate** . 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~~ **a company' s** annual or interim financial statements will not be prevented ~~,~~ or detected and corrected on a timely basis. During the years ended December 31, 2023 and 2022, we undertook remediation measures related to the ~~foregoing~~ **previously identified** material weakness in internal control over financial reporting ~~. In response to these material weaknesses~~ , **which we believe allowed us to successfully** ~~our management has expended a substantial amount of effort and resources for the remediation~~ **remediate and strengthen our** ~~of material weaknesses in~~ internal control over financial reporting. ~~Our management developed a remediation plan~~ **During the second quarter of 2023** , ~~which~~ **we completed testing of the operating effectiveness of the controls and** ~~included~~ **concluded that** ~~the hiring of accounting and finance resources, including the Chief Administrative Officer and Chief Financial Officer and Vice President, Controller with technical public company accounting and financial reporting experience, as well as other~~ -- **the** ~~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 has been accomplished over time to achieve our objectives. We believe these actions are sufficient to remediate the identified~~ material weaknesses **were** ~~and strengthen our internal control over financial reporting. During the second quarter of 2023, we completed testing of the operating effectiveness of the controls and have concluded that the material weaknesses have been~~ remediated as of June 30, 2023. Based on these measures, we believe that the previously reported material weaknesses have been remediated. However, completion of remediation procedures for the material weaknesses does not provide assurance that our process and controls will continue to operate properly or that our financial statements will be free from error. ~~If other~~ **Effective internal controls are necessary for us to provide reliable financial reports and prevent fraud. Material weaknesses could result in** material ~~weaknesses~~ **misstatements to** ~~or~~ **our annual or interim financial statements that might not** ~~control deficiencies occur in the future, we may~~ be **prevented** ~~unable to report our~~ - **or detected** ~~financial results accurately~~ on a timely basis ~~or help prevent fraud~~ , ~~which could cause our~~ - **or in delayed filing of required periodic** ~~reported~~ **reports . If we are unable to assert that our internal control over financing reporting is effective, or if our independent registered public accounting firm is unable to express an unqualified opinion as to the effectiveness of the internal control over** financial **reporting,** ~~results to be materially misstated and result in the loss of investor~~ **investors may lose** confidence **in the accuracy and completeness of** ~~or~~ **our** ~~delisting and cause~~ **financial reporting,** the market price of our ~~shares of~~ Class A common stock **could be adversely affected and we could become subject** to **litigation or investigations by Nasdaq, the SEC, or other regulatory authorities, which could require additional financial and management resources. If we identify any material weaknesses in the future, any such newly identified material weakness could limit our ability to prevent or detect a misstatement of our accounts or disclosures that could result in a material misstatement of our annual or interim financial statements. In such case, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports in addition to applicable stock exchange listing requirements, investors may lose confidence in our financial reporting and our stock price may** decline **as a result** . We cannot assure you that the ~~initiatives~~ **measures** we have taken to date, or any ~~initiatives we~~ **measures that** may **be** ~~take~~ **taken** in the future, will be sufficient to avoid potential future material weaknesses. **In addition, we may face potential for litigation or other disputes which may include, among others, claims invoking the federal and state securities laws, contractual claims or other claims arising from the restatement and material weaknesses in our internal control over financial reporting and the preparation of our Consolidated Financial Statements. We can provide no assurance that such litigation or disputes will not arise in the future. Any such litigation**

or dispute, whether successful or not, could have a material adverse effect on our business, financial condition, results of operations and cash flows. Future sales of substantial amounts of our Class A common stock, or the possibility that such sales could occur, could adversely affect the market price of our Class A common stock. Future sales in the public market of shares of our Class A common stock, including shares issued upon exercise of our outstanding stock options or warrants, or the perception by the market that these sales could occur, could lower the market price of our Class A common stock or make it difficult for us to raise additional capital. In November 2023, we filed a shelf registration statement on Form S- 3 with the SEC pursuant to which we registered for sale up to $ 150 million of any combination of our Class A common stock, preferred stock, debt securities, warrants, rights and / or units from time to time and at prices and on terms that we may determine (the " Shelf Registration Statement "). The Shelf Registration Statement also includes a prospectus covering up to an aggregate of $ 50. 0 million in shares of Class A common stock that we may issue and sell from time to time, through B. Riley Securities, Inc. (" B. Riley ") acting as our sales agent, pursuant to the sales agreement that we entered into with B. Riley in November 2023 (the " Sales Agreement "), for our " at- the- market " equity program. As of December 31, 2024, a total of 771, 721 shares of our Class A common stock, for total gross proceeds of $ 881 thousand and net proceeds of $ 828 thousand, have been issued and sold under the Sales Agreement. Due to the SEC' s " baby shelf rules, " which prohibit companies with a public float of less than $ 75 million from issuing securities under a shelf registration statement in excess of one- third of such company' s public float in a twelve- month period, we were previously limited in how much we could sell under the Shelf Registration Statement. As of the filing of this Annual Report on Form 10- K, we have a public float of greater than $ 75 million. Accordingly, we are no longer limited by the " baby shelf rules, " and may freely use the Shelf Registration Statement, which could cause our stockholders to experience dilution or could cause the price of our Class A common stock to decline Additionally, on February 11, 2025, we entered into a securities purchase agreement with certain institutional investors (the " Investors "), pursuant to which we agreed to issue and sell, in a registered direct offering directly to the Investors: (i) 4, 511, 278 shares (the " Shares ") of our Class A common stock and (ii) warrants to purchase up to 4, 511, 278 shares of our Class A common stock (the " Warrants "). Each Share and accompanying Warrant were sold together at a combined offering price of $ 1. 33. The aggregate gross proceeds from the Offering were approximately $ 6. 0 million before deducting the placement agent' s fees and offering expenses. Upon exercise or conversion, the shares underlying the Warrants and outstanding options may be resold into the public market. In the case of outstanding securities that have exercise or conversion prices that are below the market price of our Class A common stock from time to time, our stockholders would experience dilution upon the exercise or conversion of these securities. Any such resales into the public market could place downward pressure on the price of our Class A common stock 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~~ **May** ~~2022~~ **2024**, we received written notice from Nasdaq notifying us that, because the closing bid price for our Class A common stock ~~has~~ **had** fallen below $ 1. 00 per share for 30 consecutive business days, we no longer met the minimum bid price requirement for continued inclusion on The Nasdaq Global Market. ~~In February~~ **On July 24,** ~~2023~~ **2024**, we received ~~a letter~~ **written notice** from Nasdaq ~~indicating~~ that we ~~had~~ **were back in compliance with the bid price requirement. Although we have since** regained compliance with the bid price requirement ~~. However~~ **and our Class A common stock continues to trade on The Nasdaq Global Market**, 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, ~~2024~~ **2025**, Dr. Rothberg controls approximately ~~85~~ **83** % 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. **Additionally, in June 2024, our stockholders voted to approve an amendment to our certificate of incorporation, as amended (the " Charter "), to add a provision with respect to the automatic conversion of our Class B common stock effective as of December 22, 2028, which is seven years from the date of the closing of our Business Combination, 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., the Founder of Legacy Hyperfine and Liminal and a member of our board of directors, 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, ~~2024~~ **2025**, Dr. Rothberg holds approximately ~~85~~ **83** % 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 of Class A common stock 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 our ~~certificate of incorporation, as amended (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 **. As described above, in June 2024, our stockholders voted to approve an amendment to our Charter to add a provision with respect to the automatic conversion of our Class B common stock effective as of December 22, 2028** . 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~~ **our** ~~Company~~ **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~~ **our** ~~Company~~ **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 prior 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~~ **stockholder** 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~~ **Stockholder** 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, HC Sponsor LLC (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 entered into in connection with the Business Combination and the Letter Agreement entered into in connection with the Business Combination, we agreed (i) to file a registration statement with the SEC for the resale of the registrable securities under such agreements 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 investors under the subscription agreements 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 **relating to all of the registration rights set forth above** 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 involve significant expenses and 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. 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.