

Risk Factors Comparison 2025-04-09 to 2024-03-28 Form: 10-K

Legend: **New Text** ~~Removed Text~~ Unchanged Text **Moved Text Section**

The following is a summary of the principal risks and uncertainties that could materially adversely affect our business, financial condition, or results of operations. You should read this summary together with the more detailed description of risk factors below under the heading “ Risk Factors ”. · We have a history of net losses, and we expect to continue to incur losses for the foreseeable future. If we do achieve profitability, we may not be able to sustain it; · ~~We , as well as our auditors, have previously expressed substantial doubt about our ability to continue as a going concern, which may hinder our ability to obtain further financing; have previously expressed substantial doubt about our ability to continue as a going concern, which may hinder our ability to obtain further financing;~~ · We believe our current cash resources, including funding received subsequent to year end, will be sufficient to fund our current operating plans into the third quarter of ~~2024~~ **2026** , ~~approaching our final maturity repayment on our unsecured non-convertible note, which is due in September 2024.~~ We have based these estimates, however, on assumptions that may prove to be wrong, and we could spend our available financial resources much faster than we currently expect and need to raise additional funds sooner than we anticipate. If we are unable to raise additional capital when needed or on acceptable terms, we would be forced to delay, reduce, or eliminate our technology development and commercialization efforts. · **Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies and product candidates; · Our stock price may be volatile, and the value of our common stock and IPO Warrants may decline;** · We have identified a material weakness in our internal control over financial reporting. Failure to maintain effective internal controls could cause our investors to lose confidence in us and adversely affect the market price of our common stock. If our internal controls are not effective, we may not be able to accurately report our financial results or prevent fraud; · We may not be able to maintain our compliance with the continued listing requirements of the Nasdaq Capital Market and a delisting could limit the liquidity of our stock, increase its volatility and hinder our ability to raise capital. · We currently rely on our technology for use in assisting doctors to diagnose chemically painful discs causing discogenic low back pain, as well for supporting other diagnoses, treatments, and research related to lumbar disc chemistry. If we are not successful in marketing and enhancing awareness of our technology, driving adoption across our current target population, increasing referrals, and expanding the population of eligible patients, our sales, business, financial condition and results of operations will be negatively affected; · Currently, we can only market our product in the United States and certain countries observing CE mark regulations. Regulatory approvals that currently apply to our products include assessments where we determine the appropriate regulatory pathway for our products. Although we use regulatory consultants to assist in the self-registration processes and determinations, it is possible a regulator could disagree with our analysis. It is also possible that regulations relating to how we market our products may change. In addition, to maintain our ability to market our products under the approved regulations, we are required to adhere to multiple protocols in order to maintain regulatory approvals. The Company has failed to adequately follow protocols in the past and it is possible this may happen again in the future. If there is a change in our ability to market our products it may harm our sales, business, financial condition and results of operations; · Our commercial success will depend on attaining significant market acceptance of our technology among patients, clinicians (primarily spine surgeons and pain management physicians) and imaging facilities, as well as increasing the number of patients who are prescribed for use of our diagnostic technology. If we are unable to successfully achieve substantial market acceptance and adoption of our technology, our sales, business, financial condition and results of operations would be harmed; · Our commercial software products currently depend on compatible use with a limited number of MR scanners that are provided by ~~one~~ **one** MR scanner ~~vendor~~ **vendors** , **SIEMENS and PHILIPS** , which limits our ability to address the total potential patient population that our products could otherwise address in commercial sales. There are risks related to the on- going compatibility, shortages, price fluctuations, and ability to grow the number of compatible MR scanner platforms that, if realized, could harm our sales, business, financial condition, and results of operations; · If we are unable to obtain, maintain, protect, enforce and defend patent or other intellectual property protection for our technology, or if the scope of our patents and other intellectual property protections is not sufficiently broad, or as a result of our existing or any future out- licenses of our intellectual property, our competitors could develop and commercialize products similar to or competitive with our products and services, our ability to continue to commercialize our technology, or our other products and services, may be harmed. · We may be unable to compete successfully with other available alternatives for diagnosing low back pain, including, in particular, identifying painful discs causing discogenic low back pain, which could harm our sales, business, financial condition and results of operations; · If adequate reimbursement becomes unavailable for the procedures that use, or could use, our diagnostic technology, or becomes unavailable for providing other ongoing care for patients diagnosed with the assistance of our technology, it could diminish our sales, affect our ability to sell our technology profitably, or could otherwise harm our business, financial condition, and results of operations; · Our collection, use, storage, disclosure, transfer and other processing of sensitive and personal information could give rise to significant costs, liabilities and other risks, including, as a result of investigations, inquiries, litigation, fines, legislative and regulatory action and negative press about our privacy and data protection practices, which may harm our business, financial conditions, results of operations; · Our current product is supported by a single clinical study at a single clinical center involving one spine surgeon who has a financial interest in the Company. If we are unable to replicate the success of our initial clinical trial, the efficacy of our product may be in question and our sales, business, financial condition and results of operations will be harmed; · To reach the full market potential of our product, we will need to leverage advanced machine learning and artificial intelligence technologies (“ AI ”) to a larger degree than we do today. Introducing new technologies into

our products require that we secure new regulatory approvals and demonstrate additional clinical success. If we are unable to secure regulatory approvals for our new products, or if they prove incapable of demonstrating clinical success, our market opportunity will be reduced and our sales, business, financial condition and results of operations may be harmed; and · Our current product is dependent on certain processes that are not optimized to support the scaling of our technology. If we are not able to efficiently automate these processes, the Company will not be able to grow and our sales, business, financial condition and results of operations will be harmed. Risk Factors. This Annual Report on Form 10- K contains forward- looking information based on our current expectations. Because our business is subject to many risks and our actual results may differ materially from any forward- looking statements made by or on behalf of us, this section includes a discussion of important factors that could affect our business, operating results, financial condition and the trading price of our securities. This discussion should be read in conjunction with the other information in this Annual Report on Form 10- K, including our financial statements and the related notes and “ Management’ s Discussion And Analysis Of Financial Condition And Results Of Operations. ” The occurrence of any of the events or developments described below could have a material adverse effect on our business, results of operations, financial condition, prospects and securities trading prices. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations. Risks related to our Nasdaq listing We may not be able to maintain compliance with the continued listing rules of the Nasdaq Capital Market and a delisting could limit the liquidity of our stock, increase its volatility and hinder our ability to raise capital. During 2022 and, 2023, and 2024, the Company received notices from Nasdaq indicating that the Company was not in compliance with (i) Nasdaq Listing Rule 5550 (b) (1), which requires companies listed on The Nasdaq Stock Market to maintain a minimum of \$ 2, 500, 000 in stockholders’ equity for continued listing or (ii) Nasdaq Listing Rule 5550 (a) (2) which requires companies listed on The Nasdaq Stock Market to maintain a minimum of a \$ 1. 00 bid price for continued listing. The Company regained compliance with the bid price requirement after the completion of its January 2024-2025 reverse stock split. The Company recently regained compliance with the stockholders’ equity requirement after the completion of the Company’ s February January 2024-2025 public offering. Although the Company has recently resolved all pending Nasdaq listing compliance issues, there can be no assurance that the Company will be able to maintain compliance with all Nasdaq continued listing requirements in the future. If our common stock is delisted by Nasdaq, our common stock may be eligible for quotation on an over- the-counter quotation system or on the pink sheets. Upon any such delisting, our common stock would become subject to the regulations of the SEC relating to the market for penny stocks. A penny stock is any equity security not traded on a national securities exchange that has a market price of less than \$ 5. 00 per share. The regulations applicable to penny stocks may severely affect the market liquidity for our common stock and could limit the ability of shareholders to sell securities in the secondary market. In such a case, an investor may find it more difficult to dispose of or obtain accurate quotations as to the market value of our common stock, and there can be no assurance that our common stock will be eligible for trading or quotation on any alternative exchanges or markets. Delisting from Nasdaq could adversely affect our ability to raise additional financing through public or private sales of equity securities, would significantly affect the ability of investors to trade our securities and would negatively affect the value and liquidity of our common stock. Delisting could also have other negative results, including the potential loss of confidence by employees, the loss of institutional investor interest and fewer business development opportunities. Risks related to financial, operational, commercial and manufacturing matters The auditors of our December 31, 2023 and 2022 financial statements have expressed substantial doubt about our ability to continue as a going concern, which may hinder our ability to obtain further financing. Our past working capital deficiency, stockholders’ deficit and recurring losses from operations raised substantial doubt about our ability to continue as a going concern. As a result, our independent registered public accounting firm included an explanatory paragraph in its report on our financial statements for the year ended December 31, 2023, with respect to this uncertainty. As of December 31, 2023-2024, we had cash of approximately \$ 1-0, 46 million. Subsequent to December 31, 2023-2024, the Company raised capital using an equity line through two registered direct offerings and a secondary public offering (refer to Note 17 – Subsequent Events to our financial statements). We believe our current cash will fund our operating expenses and capital expenditure requirements into the third quarter of 2024 2026, approaching our final maturity repayment of our unsecured non-convertible note, which is due in September 2024. If we are unable to raise capital when needed or on acceptable terms, we would be forced to delay, reduce, or eliminate our technology development and commercialization efforts. We have incurred significant net losses since inception and anticipate that we will continue to incur net losses for the foreseeable future and may never achieve or maintain profitability. Since our inception, we have incurred significant net losses. Our net losses were \$ 6, 992, 927 and \$ 4, 911, 374 and \$ 7, 068, 593 for the years ended December 31, 2024, and 2023, and 2022, respectively. As of December 31, 2023-2024, we had an accumulated deficit of \$ 44-51, 281-262, 526-311. To date, we have devoted our efforts toward securing financing, building and evolving our technology platform, and complying with regulatory requirements as well as initiating marketing efforts for our products. We expect to continue to incur significant expenses and operating losses for the foreseeable future. We anticipate that our expenses will increase substantially if, and as, we: · hire and retain additional sales, accounting and finance, marketing and engineering personnel; · build out our product pipeline; · add operational, financial and management information systems and personnel; and · maintain, expand, protect and enforce our intellectual property portfolio. To become and remain profitable, we must enhance the marketing and commercial acceptance of our products. This will require us to be successful in a range of challenging activities, and our expenses will increase substantially as we bring these products to market. We may never succeed in any or all of these activities and, even if we do, we may never generate revenue that is significant or large enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, develop new products, expand our business or continue our operations. A decline in the value of our company also could cause stockholders to lose all or part of their investment. We have identified a material weakness in our internal control

over financial reporting. Failure to maintain effective internal controls could cause our investors to lose confidence in us and adversely affect the market price of our common stock. If our internal controls are not effective, we may not be able to accurately report our financial results or prevent fraud. Section 404 of the Sarbanes- Oxley Act of 2002, or Section 404, requires that we maintain internal control over financial reporting that meets applicable standards. We may err in the design or operation of our controls, and all internal control systems, no matter how well designed and operated, can provide only reasonable assurance that the objectives of the control system are met. Because there are inherent limitations in all control systems, there can be no assurance that all control issues have been or will be detected. If we are unable, or are perceived as unable, to produce reliable financial reports due to internal control deficiencies, investors could lose confidence in our reported financial information and operating results, which could result in a negative market reaction and a decrease in our stock price. The Company is required, pursuant to Section 404, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting (see Item 9A Management' s Annual Report on Internal Control Over Financial Reporting). We disclose any material weaknesses identified by our management in our internal control over financial reporting. As an " emerging growth company, " we will avail ourselves of the exemption from the requirement that our independent registered public accounting firm attest to the effectiveness of our internal control over financial reporting under Section 404. However, we may no longer avail ourselves of this exemption when we cease to be an " emerging growth company. " When our independent registered public accounting firm is required to undertake an assessment of our internal control over financial reporting, the cost of our compliance with Section 404 will correspondingly increase. Our compliance with applicable provisions of Section 404 will require that we incur substantial accounting expense and expend significant management time on compliance- related issues as we implement additional corporate governance practices and comply with reporting requirements. Moreover, if we are not able to comply with the requirements of Section 404 applicable to us in a timely manner, or if we or our independent registered public accounting firm identifies deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by the U. S. Securities and Exchange Commission, or SEC, or other regulatory authorities, which would require additional financial and management resources. If we continue to have material weaknesses in our internal control over financial reporting, if we are unable to comply with the requirements of Section 404 in a timely manner, if we are unable to assert that our internal control over financial reporting is effective, or if our independent registered public accounting firm is unable to express an opinion as to the effectiveness of our internal control over financial reporting, we may be late with the filing of our periodic reports, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could be negatively affected. We will need additional funding, which may not be available on acceptable terms, or at all. Failure to obtain this capital when needed may force us to delay, limit or terminate our product development efforts or other operations. We believe our current cash resources will be sufficient to fund our current operating plans into the third quarter of ~~2024~~ **2026**, ~~approaching our final maturity repayment of our unsecured non- convertible note, which is due in September 2024.~~ We expect our expenses to increase in connection with our ongoing activities, particularly as we continue to invest in clinical studies, sales, marketing, and engineering resources to bring our products to market. Building and scaling technology products is a time- consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary user experience required to obtain market acceptance and achieve meaningful product sales. In addition, our product candidates, once developed, may not achieve commercial success. The majority of revenue will be derived from or based on sales of software products that may not be commercially available for many years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all. Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies and product candidates. We may seek additional capital through a combination of public and private equity offerings, debt financings, strategic partnerships and alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. The incurrence of indebtedness would result in increased fixed payment obligations and could involve restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, or our other product candidates, or grant licenses on terms unfavorable to us. We are highly dependent on our senior management team and key personnel, and our business could be harmed if we are unable to attract and retain personnel necessary for our success. We are highly dependent on our senior management and key personnel. Our success will depend on our ability to retain senior management and to attract and retain qualified personnel in the future, including sales and marketing professionals, engineers, scientists, clinical trial specialists and other highly skilled personnel and to integrate current and additional personnel in all departments. The loss of members of our senior management, marketing professionals, engineers, scientists and clinical trial specialists could result in delays in product development and harm our business. Competition for skilled personnel in our market is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms, or at all. To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have issued stock options that vest over time. The value to employees of stock options that vest over time may be significantly affected by fluctuations in our stock price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management and other key personnel may terminate their employment with us on short notice. Our employment arrangements with our employees provide for at- will employment, which means that any of our employees could leave our employment at any time, with or without notice. We also do not maintain " key man " insurance policies on the lives of these individuals or the

lives of any of our other employees. Our MR data post- processing products currently depend on compatible use with only a limited number of MR scanners that are provided only by one manufacturer of MR devices. Our MR data post- processing software products are only compatible for post- processing disc MRS data acquired via certain scanner models and operating configurations provided ~~only by one two~~, third- party scanner ~~vendor vendors~~ - SIEMENS **and Philips**. There are risks associated with our reliance on ~~SIEMENS these MR scanner vendors~~, and / or the MR service providers who own and operate the SIEMENS **or Philips** scanners, to maintain those scanners and their operating configurations in a manner that continues to support compatibility with our products. There are also risks that current compatible scanner platforms may become incompatible as a result of changes made to those scanners by SIEMENS **or Philips**, or by the scanner owner or related service provider, which would frustrate our ability to continue supporting that MR provider customer with our products. There are also risks that these SIEMENS **or Philips** scanners do not perform reliably as intended or expected in performing data acquisition exams as required by our post- processing products, which would also frustrate the ability for our products to perform as intended. There is also a risk that SIEMENS **and Philips combined** ~~loses- lose its their~~ install base of compatible MR Scanners due to cannibalization by other non- compatible replacement scanner sales or ~~fails- fail~~ to grow ~~its their~~ install base of those compatible scanners, which could adversely affect the number and locations of compatible scanners for our own market share and penetration. Manifestations of these risks becoming actually realized in the marketplace could harm our business, financial condition, and results of operations. We are not subject to any exclusivity agreement or obligations with SIEMENS **or Philips**, nor do we have any fee sharing, royalty, or other exchange of moneys or payments between us and Siemens **or Philips at this time**. ~~The~~ **Initially, the** nexus for our focused relationship with Siemens resulted from our determination that SIEMENS scanner models were optimally positioned to support our product. We have had a collaborative relationship with Siemens since 2011 and have been party to a Collaborative Agreement with Siemens since October of 2017, The Collaborative Agreement is terminable ~~at any time by either party if such party is of the opinion that the goals of the Collaborative Agreement cannot be achieved for technical, economic and / or clinical reasons.~~ **Subsequent to our newly launched relationship and capability with Philips, the critical single source relationship with Siemens has been largely mitigated and is now shared between two of the top three providers of MRI systems worldwide**. If we are not successful in enhancing awareness of our technology, driving adoption across our current target population, increasing referrals from surgeons and clinicians, and expanding the population of eligible patients, our sales, business, financial condition and results of operations will be negatively affected. Our business depends on our ability to successfully market our technology, which includes increasing the number of patients scanned with our technology, increasing adoption of our technology and driving utilization of our technology by surgeons and clinicians. Additionally, our technology is primarily recommended and implemented to provide advanced diagnosis and management of spine and back pain, in particular, for diagnosing painful discs causing discogenic low back pain. Therefore, we are dependent on widespread market adoption of our technology. While we intend to expand the population of patients we can provide with our diagnostic technology as well as increase the number of physicians, surgeons and clinicians that can prescribe technology, there can be no assurance that we will succeed. The commercial success of our technology will continue to depend on a number of factors, including the following: · the actual and perceived effectiveness, safety and reliability, and clinical benefit, of our technology, especially relative to alternative diagnostic systems and devices; · the prevalence and severity of any adverse patient events involving the use of our technology; · the degree to which physicians, surgeons and clinicians, patients and imaging centers adopt our technology; · the availability, relative cost and perceived advantages and disadvantages of alternative technologies, or other diagnostic or treatment methods, for spine and back pain; · the results of additional clinical and other studies relating to the health, safety, economic or other benefits of our technology; · whether key thought leaders in the medical community accept that our clinical efficacy and safety results are sufficiently meaningful to influence their decision to adopt our technology over other spine and back pain diagnostics; · the extent to which we are successful in educating physicians, surgeons, clinicians, patients, and imaging facilities about the appropriate (and inappropriate) uses and benefits of our technology; · the strength of our marketing and distribution infrastructure, including our ability to drive adoption and utilization of our technology, as well as our ability to develop and maintain relationships with MRI manufacturers and imaging centers; · our ability to obtain, maintain, protect, enforce and defend our intellectual property rights, in and to our technology; · our ability to maintain compliance with all legal and regulatory requirements, including those applicable to our technology; · our ability to maintain our contractual relationships with our vendors and component suppliers, including single- source vendors and suppliers through which we obtain critical components for (or compatible use with) our technology; · the establishment and continued reimbursement coverage of and adequate payment for the use of our technology and · our ability to continue to attract and retain key personnel. If we fail to successfully market and sell our technology cost- effectively and maintain and expand our market share, our sales, business, financial condition and results of operations will be negatively affected. Our commercial success will continue to depend on attaining significant market acceptance of our technology among physicians, surgeons, patients, clinicians and imaging facilities, and increasing the number of patients diagnosed by our technology. Our commercial success will depend, in large part, on the further acceptance by surgeons, physicians, clinicians, patients and imaging facilities of our technology as safe, useful, cost- effective, and that it can increase the number of patients that are diagnosed. We cannot predict how quickly, or if at all, additional surgeons, physicians, clinicians, patients and imaging facilities will adopt our technology over competing diagnostic platforms for support in on- going care and treatment options that are expected to be supported by the intended diagnostic uses of our technology. For example, surgeons, other physicians, clinicians, patients, and imaging facilities may be reluctant to use our technology due to familiarity with pre- existing diagnostic systems that are more established or an otherwise resistance to adopt new technologies or change current practices. Our ability to grow sales of our technology and drive market acceptance will depend on successfully educating surgeons, physicians, clinicians, patients and MR imaging facilities on the relative benefits of our Technology. We may be unable to compete successfully with other diagnostic options for low back pain,

or may be unable to continue providing value for supporting new treatments that may not need the diagnostic information our products provide. The medical device industry is intensely competitive, subject to rapid change and significantly affected by new product introductions and other market activities of industry participants. Our current competition primarily resides with the diagnostic standards over which our products are intended to improve – in particular, X-ray, lumbar MRI, and PD. Our products are positioned for synergistic use with lumbar MRI, and to enhance the diagnostic value of lumbar MR exams. However, the existing reliance on lumbar MRI as a standard of care for our DLBP indication, and on PD in some medical practices, and the potential for other enhancements to those platforms and techniques, nonetheless also represents a competitive threat. To the extent that these other platforms represent our primary competitors, they are mainly provided by large, well-capitalized companies with significant market share and resources. Most of our competitors have more established sales and marketing programs than us and have greater name recognition. These competitors also have long operating histories and may have more established relationships with potential customers. Also, there can be no assurance that other companies or institutions will not succeed in developing or marketing devices and products that are more accurate, useful, effective or safer than our technology or that would render our technology obsolete or noncompetitive. Adoption of our technology depends on positive clinical data as well as clinician acceptance of the data and our products, and negative clinical data or perceptions among these clinicians would harm our sales, business, financial condition, and results of operations. The rate of adoption and sales of our products are heavily influenced by clinical data. We have published positive clinical data from an Institutional Review Board (“IRB”), approved more than 100 patient single center trial in a major peer-reviewed spine journal which showed both: (a) high diagnostic accuracy against provocation discography controls, and (b) much higher patient success outcomes for surgeries that treated discs identified as painful using our products, versus much lower success rates when discs diagnosed as painful with our products were left untreated. However, there can be no assurance that our clinical data will continue to be positive for our ongoing or future clinical studies. Additionally, there can be no assurance that future clinical studies, including those to continue demonstrating the diagnostic accuracy and value of our products in currently approved patient populations and those to support label retention and expansion for our products, will demonstrate diagnostic acuity or value. Unfavorable or inconsistent clinical data from ongoing or future clinical studies conducted by us, our competitors, or third parties, or the potential for negative interpretation of our clinical data by customers, competitors, patients, and regulators, or the potential for finding new or more frequent adverse events related to the use of our products could harm our sales, business, financial condition, and results of operations. If adequate reimbursement is not available for the procedures implementing our technology, or for clinicians to provide ongoing care for patients diagnosed with our technology, it could diminish our sales or affect our ability to sell our technology. Our ability to increase sales of our technology depends, in significant part, on the availability of adequate financial coverage and reimbursement from third-party payors, which include: (i) governmental payors such as the Medicare and Medicaid programs in the United States; (ii) private managed care organizations; and (iii) private health insurers. Third-party payers determine which services and treatments they will cover and establish reimbursement rates for those treatments. While we have secured certain reimbursement codes against which the use of our products can potentially be billed, we do not yet currently bill any third-party payers directly for our technology. The cost of our customers using our technology is currently being paid for by either: (i) billing patients to pay directly (ii) allocation at least in part against payments received by healthcare providers for other procedures conducted in association with the use of our technology, or (c) third-party payer reimbursement payments to ~~one or several~~ of our customers for ~~approximately 20 less than 10~~ patients through the date of this ~~prospectus filing~~. A failure to obtain wide coverage and adequate reimbursement for using our technology in conducting our new diagnostic procedures, or for clinicians providing ongoing patient care based on or related to our diagnostic results could diminish our sales and affect our ability to sell our technology. If adequate reimbursement for our temporary Category III CMS Code designation for our products cannot be obtained or we are not successful in obtaining conversion to permanent Category I codes at an adequate reimbursement level, it would diminish our sales and would affect our ability to market our technology. On January 1, 2021, our Category III CPT Codes became effective (see “Business”, “Reimbursement” above). Category III codes represent the first step in the reimbursement process (See “Business” “Reimbursement” above). The effectiveness of our Category III codes commenced a five-year period in which, in order to maintain our Category III status, we are required to demonstrate that the medical community needs (“Clinical Needs”) the NOCISCAN product. Clinical Needs would be demonstrated to the CPT Committee based on the volume at which our Category III codes are billed by imaging centers and physicians. In addition to demonstrating that there is Clinical Needs, we also are required to show that NOCISCAN is clinically effective as indicated by patients having better outcomes when NOCISCAN reports are used to help guide surgical treatments. We expect to show clinical effectiveness through a combination of clinical registries and clinical studies that build upon our published clinical study the CPT committee used to create our Category III CPT codes. However, if we are not able to demonstrate Clinical Needs, nor that NOCISCAN is clinically effective, our revenue would be limited to a direct patient payment model, which will severely limit our ability to market our products and generate sufficient revenue to continue market our technology. Further, for us to obtain a conversion from our CPT codes from Category III to Category I, we will need to attract a significant larger number of surgeons and imaging centers to adopt our technology and thereby increase the volume of reimbursement claims data needed for the CPT committee to determine that our product is needed in the healthcare marketplace. In addition to generating clinical use volume, we will also need to demonstrate the ongoing clinical efficacy of our products to secure adequate reimbursement from payers. A failure to convert Category III codes to Category I codes will ultimately make us more dependent on a patient pay model which will significantly diminish our sales and affect our ability to market our technology. Use of our technology requires appropriate training for proper use of our products, and inadequate training may lead to negative patient outcomes, which could harm our business, financial condition, and results of operations. The successful use of our technology depends, in part, on the training and skill of referring doctors and other healthcare providers for appropriately prescribing our diagnostic exam for the correctly indicated patients and anatomy, and properly interpreting the results from using our product as indicated under our

related IFUs. It also depends upon MR technicians and operators appropriately implementing and using our technology as indicated under our related IFUs. MR technicians and operators could also experience difficulty with the steps and techniques necessary to successfully implement and use our technology protocols. We cannot guarantee that all medical and MR technician professionals will have the necessary skills and training, according to our instructions for use, or will sufficiently comply with that training and instructions for use in order to properly prescribe and interpret the results of our diagnostic imaging platform. We cannot be certain that surgeons, other physicians, MRI technicians or operators, or other healthcare providers that use our technology will have received sufficient training or will continue to comply with that training in their on- going practice in using our technology. If physicians and surgeons utilize our technology incorrectly or, without adhering to or completing all relevant training according to our instructions, the utility and value of our diagnostic products and their related patient outcomes from on-going care following that diagnostic work- up may not be consistent with the outcomes achieved in our clinical studies or otherwise expected or desired by such care providers or the patients themselves. Adverse treatment outcomes that could potentially arise from improper or incorrect use of our technology may negatively impact the perception of patient benefit and safety of our technology, notwithstanding results from our clinical studies. These results could limit adoption of our technology, which would harm our sales, business, financial condition, and results of operations. We expect to increase the size of our organization in the future, and we may experience difficulties in managing this growth. If we are unable to manage the anticipated growth of our business, our future revenue and operating results may be harmed. As of December 31, 2023-2024, we had 4-5 full- time employees, 2-1 part- time employees- employee, 1 full- time consultant, and 3-2 part- time consultants. As our sales and marketing strategies develop, and as we transition into operating as a public company, we expect to need additional managerial, operational, sales, marketing, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including: · identifying, recruiting, integrating, maintaining and motivating additional employees; · managing our internal development efforts effectively, while complying with our contractual obligations to contractors and other third parties; and · improving our operational, financial and management controls, reporting systems and procedures. Our future financial performance and our ability to successfully market and sell our technology will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of attention away from day- to- day activities in order to devote a substantial amount of time to managing these growth activities. We may not be able to achieve or maintain satisfactory pricing and margins for our NOCISCAN disc MRS diagnostic software products and related services, which could harm our business and results of operations. Software products classified as medical devices have a history of price competition and we can give no assurance that we will be able to maintain satisfactory prices for our technology. The pricing of our technology could be impacted by several factors, including pressure to reduce prices by our customers due to a decline in the amount that third- party payers reimburse for diagnostic procedures using our technology or for clinicians providing ongoing patient care related to the diagnostic information we provide. A decline in the amount that third- party payers reimburse our customers for ongoing patient care could also make it difficult for us to maintain procedural volume without a corresponding reduction in prices for our products. If we are forced to lower the price we charge for our technology, our gross margins will decrease, which will harm our ability to invest in and grow our business. If we are unable to maintain our prices, or if our costs increase and we are unable to offset such increase with an increase in our prices, our margins would erode and could harm our business, financial condition, and results of operations. Our results of operations may be harmed if we are unable to accurately forecast customer demand for our technology. Our ability to accurately forecast demand for our products could be negatively affected by many factors, including (i) our potential failure to accurately manage or execute our expansion strategy, (ii) new product introductions by competitors, (iii) an increase or decrease in customer demand for our products or for other competing products, (iv) our failure to accurately forecast customer adoption of new products, (v) unanticipated changes in general market conditions or regulatory matters and (vi) weakening of economic conditions or consumer confidence in future economic conditions. Software processing capacity, data storage, and related computer hosting resources in excess of customer demand may result in financial write- downs or write- offs, which would cause our gross margin to be adversely affected and could impair the strength of our brand. Conversely, if we underestimate customer demand for our products, our technical and IT resource support team, software processing and storage resources, and computing architectures may not be able to support sufficient processing requirements to meet the demand for our products; and this could result in lost sales and damage to our reputation and customer relationships. In addition, if we experience a significant increase in demand, additional computing and storage capacity and resources, and additional technical support personnel required to support the increased demand may not be available when required or on terms that are acceptable to us, or at all, which may negatively affect our sales, business, financial condition, and results of operations. Risks related to government regulation and our industry Our operations and technology are subject to pervasive and continuing FDA regulatory requirements, and failure to comply with these requirements could harm our business, financial condition and results of operations. Before a regulated new medical device or service, or a new intended use for an existing device or service, can be marketed in the United States, a company must first receive either 510 (k) clearance, or a PMA from the FDA, unless an exemption applies. In the 510 (k) clearance process, before a device may be marketed, the FDA must determine that: (i) a proposed device is substantially equivalent to a legally- marketed predicate device, which includes a legal marketed device that has been previously cleared through the 510 (k) process, (ii) was legally marketed prior to May 28, 1976 (pre- amendments device), (iii) was legally marketed pursuant to an approved PMA and later down- classified, or (iv) is covered by a classification regulation created through the de novo review process. In the process of obtaining PMA approval, which the FDA could potentially require in the future for our products, 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, preclinical, clinical study, manufacturing and labeling data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life- sustaining, life- supporting or implantable devices. We believe that one of our products under the NOCISCAN Suite,

NOCICALC, is a Class I 510 (k)- exempt medical device, which only requires registration and no pre- market review with the FDA, and which we registered as such with the FDA. We also believe the other of our products in the suite, NOCIGRAM, is “ Clinical Decision Support Software ” under the 21st Century Cures Act and as such, is not considered a medical device, and thus is not regulated by the FDA. Accordingly, we believe that our current products do not require FDA clearance or approval under either 510 (k) or PMA approval pathways. However, there can be no assurance that in the future, the FDA will not determine that PMA approval, de novo classification, or 510 (k) clearance is required for our products. If the FDA were to make such a determination, we would not be able to sell or market our products without or until securing such approval or clearance and may be subject to potential fines and other penalties or remedial actions for illegally marketing or selling an unapproved medical device, which would affect our sales, business, financial condition, and results of operation. If we are unable to expand the labeling claims for using our technology to include additional indications, our growth potential could be harmed. We intend to seek expanded labeling claims for our technology in the future, including for example: (i) extending the intended indications for use to include disc MRS along the thoracic or cervical spine, (ii) incorporating certain MRI image post- processing along with MRS data post- processing, and (iii) real- time post- processing of MRS exam data during the exam itself via our software installed and operated within the MR scanner software environment (vs. our current products which are for cloud- hosted post- processing of MRS data that is transferred to us, following the MRS exams, via our own remote computing resources). If regulatory clearance or approval is required to expand the use of our technology, and which clearance and approval may require clinical trial results, we could incur substantial costs and the attention of management could be diverted throughout this process. However, there can be no assurance we will be able to obtain and maintain necessary clearance or approvals for additional uses of our technology, or even if obtained, that the broadened use of our technology would be accepted or adopted by intended users, thus limiting the growth potential of our business. Our medical device products may be subject to recalls, which could divert managerial and financial resources, harm our reputation and our business. The FDA has the authority to require the recall of medical device products in certain circumstances. A government mandated or voluntary product recall by us could occur because of device malfunctions or other adverse events, such as quality- related issues resulting from product operating malfunctions or defects. Any future recalls of our products could divert managerial and financial resources, harm our reputation and negatively impact our business. If we initiate a correction or removal of certain of our products from the market to reduce a risk to health posed by the device, we would be required to submit a Correction and Removal report to the FDA and, in many cases, similar reports to other regulatory agencies. This report could be classified by the FDA as a device recall which could lead to increased scrutiny by the FDA and our customers regarding the quality and safety of our products. Furthermore, the submission of these reports could be used by competitors against us and could harm our reputation, which could cause customers to delay purchase decisions, cancel orders or decide not to purchase our products and could cause patients to lose trust in our technology. We may experience difficulties outside the US in obtaining or maintaining regulatory clearance or approval, or exemptions therefrom, or in successfully gaining third- party reimbursement or marketing our technology, even if approved or otherwise legally marketed. Our NOCISCAN product suite was initially commercialized as a Class I medical device under European Commission regulations. The process did not require pre- market submission, review, or certification by a Notified Body in order to be CE marked. A “ Notified Body ” is an organization designated by an EU country to assess the conformity of certain products before being placed on the market. For commercialization outside the United States, in particular the European Union (“ EU ”) and United Kingdom (“ UK ”), the Company, in conjunction with our regulatory consultants, determined NOCISCAN to be a Class I medical device, for which we secured a CE mark via self- certification. As such, we self- certified our product for the CE mark under a Declaration of Continuity (“ DOC ”) filed by us as part of a dossier with a qualified EU Representative. Since self- certification was completed by the Company, the EU adopted Medical Device Regulation (EU) 2019 / 1020, known as MDR, that went into effect on July 16, 2021. Under these new regulations, we believe NOCISCAN to be considered a Class II (a) device that requires re- certification for CE mark by a Notified Body prior to May 2024. Notified Bodies carry out tasks related to conformity assessment procedures set out in the applicable legislation, when a third party is required. Class II (a) device certification is subject to additional requirements for approval beyond our existing submissions, including requiring pre- market review and CE mark approval by a Notified Body, and which may require submission and approval of supportive clinical data. We are currently seeking to identify, but have not yet engaged, a Notified Body for this purpose. The available number of Notified Bodies, and those engaging new company applicants, has been significantly reduced in recent years and the ability for conducting a Notified Body review and CE mark approval can typically take more than a year. Certain aspects of the new MDR also place new requirements on Class I medical devices that are not subject to the extended 2024 grace period and became effective as of May 2021. This applies to new required policies and practices for post- market surveillance of our products. While we are not currently compliant with these new requirements, we are in the process of updating our policies and practices and taking the corrective actions to achieve and maintain ongoing compliance. We believe the actions we are taking are sufficient to support the continuance of our commercial activities in the EU under our CE mark without adverse penalties or other consequences. However, there is a risk that one or more regulatory body or agency in the EU may determine otherwise, either with respect to our prior non- compliance that has since been corrected or with respect to the sufficiency of our corrective actions, and which could result in us incurring certain penalties or other consequences. If we are unable to engage or receive CE mark approval from a Notified Body under the MDR by the May 2024 grace period deadline, or are determined to be non- compliant with MDR regulations not subject to the grace period and therefore applicable to us as of May 2021, we could lose our CE mark, and may become unable to continue promoting or selling our products for commercial use in the EU, UK, or other countries that relate their medical device regulations to a CE mark. In conjunction with Brexit, medical devices in the UK are no longer governed by CE regulations. As such, the UK has introduced the UKCA marking system which largely follows the CE marking regulations to include permitting use of the same submissions for approval. The major difference post- Brexit is that CE marking is regulated by the EU and UKCA marking is regulated by

the UK. The only practical implication to the Company is the requirement of a Notifying Body within both the EU and the UK. If the Company is successful in meeting all requirements of the CE mark under MDR set forth above, the company believes it will meet all requirements for UKCA marking. While we are not currently compliant with new requirements in the UK, we are in the process of updating our policies and practices and taking what we believe are corrective actions to achieve and maintain ongoing compliance in the UK. We believe our activities are sufficient to support the continuance of our commercial activities in the UK under our CE mark without adverse penalties or other consequences. However, there is a risk that one or more regulatory body or agency in the UK may determine otherwise, either with respect to our prior non-compliance that we believe has been corrected or with respect to the sufficiency of those corrective actions and which could result in us incurring certain penalties or other adverse consequences to our business. There can be no assurance that we can obtain a UKCA mark and if we are not able to secure a UKCA mark, we will lose our ability to conduct business in the UK. Sales of our technology outside of the United States will be subject to foreign regulatory requirements governing clinical studies and marketing approval, as well as additional post-market requirements. We would incur substantial expenses in connection with any international expansion. Additional risks related to operating in foreign countries include: · differing, and potential changes in, regulatory requirements in foreign countries, including with respect to data privacy and security; · differing, and potential changes in, reimbursement regimes in foreign countries, including price controls; · unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements; · economic weakness, including inflation, or political instability in particular foreign economies and markets; · compliance with tax, employment, immigration and labor laws for employees living or traveling abroad; · foreign taxes, including withholding of payroll taxes; · foreign currency fluctuations, which could result in increased operating expenses or reduced revenue; · difficulties staffing and managing foreign operations; · workforce uncertainty in countries where labor unrest is more common than in the United States; · potential liability under the U. S. Foreign Corrupt Practices Act of 1977, as amended, or the FCPA, or comparable foreign regulations; · challenges enforcing our contractual and intellectual property rights as well as intellectual property theft or compulsory licensing, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States; and · business interruptions resulting from geopolitical actions, including war and terrorism. These and other risks associated with international operations may harm our ability to attain or maintain profitable operations internationally, which would harm our growth potential. Furthermore, there are foreign privacy laws and regulations that impose restrictions on the collection, use, storage, disclosure, transfer and other processing of personal data, including health information. For example, the European Union General Data Protection Regulation (“GDPR”), imposes stringent data protection requirements, including, for example, more robust disclosures to individuals, a strengthened individual data rights regime, shortened timelines for data breach notifications, limitations on retention of information, increased requirements pertaining to special categories of data, such as health data, and additional obligations regarding third-party processors in connection with the processing of the personal data. Our failure to comply with the GDPR or other applicable foreign privacy laws or regulations or significant changes in the laws and regulations restricting our ability to obtain or use required patient information could significantly impact our business and our future business plans. If we fail to comply with fraud and abuse and other healthcare laws and regulations in the U. S. and internationally including those relating to kickbacks and false claims for reimbursement, we could face substantial penalties and our business, financial condition and results of operations could be harmed. Healthcare providers play a primary role in the distribution, recommendation, ordering and purchasing of any of our products. Through our arrangements with healthcare professionals and hospital facilities, we are exposed to broadly applicable anti-fraud and abuse, anti-kickback, false claims and other healthcare laws and regulations that may constrain our business, our arrangements and relationships with customers, and how we market, sell and distribute our marketed medical devices. We have a compliance program, code of conduct and associated policies and procedures, but it is not always possible to identify and deter misconduct by our employees, contractors, and other third parties, including our customers, and the precautions we take to detect and prevent noncompliance may not be effective in protecting us from governmental investigations for failure to comply with applicable fraud and abuse or other healthcare laws and regulations. In the United States, we are subject to various state and federal anti-fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and federal civil False Claims Act, or the FCA. Our relationships with physicians, other health care professionals and hospitals are subject to scrutiny under these laws. There are also similar laws in other countries that we may become subject to if we expand internationally. The laws that may affect our ability to operate include, among others: · The Anti-Kickback Statute, which prohibits, among other things, knowingly and willingly soliciting, offering, receiving or paying remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual, or the purchase, order or recommendation of, items or services for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs; · The federal civil and criminal false claims laws, including the FCA, and civil monetary penalties laws, which prohibits, among other things, persons or entities from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment of government funds and knowingly making, using or causing to be made or used, a false record or statement to get a false claim paid or to avoid, decrease or conceal an obligation to pay money to the federal government; · The Health Insurance Portability and Accountability Act of 1996, or HIPAA, which applies to our customers and some of their downstream vendors and contractors, imposes criminal and civil liability for, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payers, or knowingly and willfully falsifying, concealing or covering up a material fact or making a materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false, fictitious or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items or services; · Various state laws governing the privacy and security of personal information, including the California Consumer Privacy Act (“CCPA”), which became effective on January 1, 2020, which regulates the processing of personal information of California

residents and increases the privacy and security obligations of covered companies handling such personal information. The CCPA requires covered companies to, amongst other things, provide new and additional disclosures to California residents, and affords such residents new abilities to access their personal information and opt out of certain sales of personal information; and

- The federal Physician Payments Sunshine Act, also known as Open Payments, requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually, with certain exceptions to the Centers for Medicare and Medicaid Services, or CMS, information related to payments or other "transfers of value" made to certain physicians or other healthcare providers, as defined by such law, and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually to CMS ownership and investment interests held by physicians and their immediate family members. State and federal regulatory and enforcement agencies continue to actively investigate violations of healthcare laws and regulations, and the U. S. Congress continues to strengthen the arsenal of enforcement tools. Enforcement agencies also continue to pursue novel theories of liability under these laws. In particular, government agencies have increased regulatory scrutiny and enforcement activity with respect to manufacturer reimbursement support activities and patient care programs, including bringing criminal charges or civil enforcement actions under the Anti- Kickback Statute, the FCA and HIPAA's healthcare fraud and privacy provisions. Achieving and sustaining compliance with applicable federal and state anti- fraud and abuse laws may prove costly. If we, or our employees, are found to have violated any of the above laws we may be subjected to substantial criminal, civil and administrative penalties, including imprisonment, exclusion from participation in federal healthcare programs, such as Medicare and Medicaid, and significant fines, monetary penalties, forfeiture, disgorgement and damages, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results. Any action or investigation against us for the violation of these healthcare fraud and abuse laws, even if successfully defended, could result in significant legal expenses and could divert our management's attention from the operation of our business. Companies settling FCA, Anti- Kickback Statute or civil monetary penalties law cases also may be required to enter into a Corporate Integrity Agreement with the OIG, in order to avoid exclusion from participation (which results in a loss of coverage for their products) in federal healthcare programs such as Medicare and Medicaid. Corporate Integrity Agreements typically impose substantial costs and operational burdens on companies to ensure compliance. Defending against any such actions can be detrimental to our reputation and brand and can otherwise be costly, time- consuming and may require significant personnel resources, and may harm our business, financial condition and results of operations. We have financial relationships with certain physicians and health care providers, research investigators, and authors for our clinical or scientific publications that may be deemed a conflict of interest and may be subject to certain statutory or regulatory requirements, under which a failure to comply could lead to enforcement actions against us and other negative consequences for our business. We have certain financial relationships with medical doctors and other healthcare providers who are investors and shareholders in our Company and / or paid consultants, clinical investigators, or speakers promoting our products and clinical results, some of whom are also our customers who pay us for patients receiving a NOCISCAN exam, or otherwise prescribe and get paid for interpreting a NOCISCAN exam. There are risks that one or more of these relationships may be determined to be a conflict of interest and be in violation of applicable laws, regulations, or guidelines, which could potentially subject us to significant fines or curtailment of our active commercial operations, and which could also potentially harm our reputation in the marketplace. If we are deemed to not comply with requirements governing the industry's relationships with physicians or there is an investigation into our compliance by the Office of the Inspector General, the Department of Justice, states' attorney generals or other government agencies, it could harm our sales, business, financial condition, and results of operations. Regulatory compliance is expensive, complex and uncertain, and a failure to comply could lead to enforcement actions against us and other negative consequences for our business. The FDA, EU, and other foreign regulatory agencies or governing bodies, regulate certain of our products as medical devices. Complying with these regulations is costly, time- consuming, complex and uncertain. For instance, before a new medical device, or a new intended use for an existing device, can be marketed in the United States, a company must first submit and receive either 510 (k) clearance, de novo approval, or approval of a PMA from the FDA, unless an exemption applies. FDA regulations and regulations of similar agencies are wide- ranging and include, among other things, oversight of: · product design, development, manufacturing (including suppliers) and testing; · laboratory, preclinical and clinical studies; · product safety and effectiveness; · product labeling; · product storage and shipping; · quality assurance policies, practices, and record keeping; · pre- market clearance or approval; · marketing, advertising and promotion; · product sales and distribution; · product changes; · product recalls; and · post- market surveillance and reporting of deaths, serious injuries, certain malfunctions, and related corrective actions. Further, improvements of our existing technology, any potential new technology, and new indications for use of our current technology may be subject to extensive regulation, and we may require permission from regulatory agencies and ethics boards to conduct clinical studies, as well as clearance or approval from the FDA, or other such foreign regulatory agencies or governing bodies, prior to commercial sale. In order to commercialize and distribute our products in markets outside of the United States, it will require approval from, or otherwise meeting the requirements of, non- U. S. regulatory agencies. The FDA and foreign regulatory bodies can delay, limit or deny clearance or approval (or otherwise a related "exemption") for a device for many reasons, including: · our inability to demonstrate to the satisfaction of the FDA or the applicable regulatory entity or notified body that our products are safe or effective for their intended uses; · disagreement of the FDA or the applicable foreign regulatory body with the design or implementation of our clinical studies or the interpretation of data from clinical studies, or with the regulatory classification or related pre- market regulatory pathway pursued by the Company for our products; · adverse device effects experienced by participants in our clinical studies; · the insufficiency of data from our preclinical studies and clinical studies to support clearance or approval, where required; · our inability to demonstrate that the clinical and other benefits of our products outweigh the risks; · failure of our manufacturing process or facilities to meet

applicable requirements; and · significant changes to the policies or regulations of the FDA or applicable foreign regulatory bodies that render our clinical data or regulatory classifications, pre- market review pathways, or related filings insufficient for approval or that otherwise prevent us from legally marketing our products. Future clinical studies may be delayed, suspended or terminated for many reasons, including to support reimbursement coverage and certain potential label expansions for additional indications, which will increase our expenses and delay the time it takes to secure reimbursement coverage or support label expansion for additional indications. We plan to continue to develop and execute clinical studies to support reimbursement coverage for using our products, label retention for our products, label expansion for our products into additional claims for diagnosing painful discs and improving patient outcomes and additional thoracic and cervical discogenic back pain patient populations. We may also develop and execute clinical studies for new products or for label expansion for our current products into patient populations suffering from other pain or tissue chemistry- mediated conditions. We may also develop modifications to our products, and conduct related clinical studies, related to expanding indications for post- processing data from other MRS applications in the body. We do not know whether future clinical studies will begin on time, will need to be redesigned, have an adequate number of patients enrolled or be completed on schedule, if at all. The commencement and completion of clinical studies to support label retention and expansion for additional indications or for new products may be delayed, suspended or terminated as a result of many factors, including: · the delay or refusal of regulators or Institutional Review Boards, or IRBs, to authorize us to commence a clinical study at a prospective trial site; · changes in regulatory requirements, policies and guidelines; · delays or failure to reach agreement on acceptable terms with prospective clinical research organizations, or CROs, and clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites; · delays in patient enrollment and variability in the number and types of patients available for clinical studies, ~~including due to COVID-19 or other disease outbreak, and delays in or the inability to monitor enrolled patients, including due to COVID-19 or other disease outbreak~~; · the inability to recruit, enroll, or retain a sufficient number of patients; · deviations by our CROs or clinical sites from the trial protocol or study discontinuation by participants, investigators, or study sites; · safety or tolerability concerns that could cause us to suspend or terminate a trial if we find that the participants are being exposed to unacceptable health risks; · regulators, Institutional Review Boards (“ IRBs ”), Ethics Committees or Data Safety Monitoring Boards requiring that we or our investigators or study sites suspend or terminate clinical studies for various reasons, including noncompliance with GCP or other regulatory requirements or safety concerns; · lower than anticipated retention rates of patients and volunteers in clinical studies; · failure of our CROs or clinical studies sites to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all; · delays relating to identifying and engaging with and adding new clinical study site that have access to compatible MR scanners for using our products; and · exceeding budgeted costs. In addition, if the FDA concludes that we have not adequately disclosed financial interests of our investigators or if our disclosed financial relationships with investigators result in a perceived or actual conflict of interest that may have affected the interpretation of a study, the integrity of the data generated at the applicable clinical study site or the utility of the clinical study itself, FDA may refuse to consider data from the study. This could result in delay or rejection by the FDA. Any such delay or rejection could prevent us from supporting label retention and expansion for our products. A failure to comply with governmental regulatory requirements would have a negative impact upon our business. Failure to comply with applicable U. S. requirements regarding promoting, manufacturing, labeling, and establishing and complying with appropriate quality assurance policies, systems, and practices for our products may subject us to a variety of administrative or judicial actions and sanctions. We currently offer the NOCISCAN product suite via two interactive products, NOCICALC, which is listed with the FDA as a Class I, 510 (k)- exempt product, and NOCIGRAM, a type of medical software that we have concluded is exempt from medical device regulation by the FDA pursuant to the 21st Century Cures Act. This product suite is also self- certified and CE Marked as a Class I medical device under MDD requirements, while we believe it is considered a Class II medical device and requiring Notified Body review and certification under newer MDR regulations (subject to a grace period until **May December 2024-2028**). These products are marketed and sold with certain labeling and related instructions for use and are promoted by various marketing and sales materials and related human interactions via our personnel and our target customers. We have also established, and operate under, certain quality assurance systems, policies, and procedures under our QMS intended to be compliant with applicable requirements for all relevant territories and jurisdictions related to our commercial activities. In the event that our establishment, maintenance, marketing, promotion, labeling, or execution of these products, or these systems, policies, practices, or procedures, are determined to be inadequate or non- compliant with applicable regulatory requirements, such defect could result in certain potential enforcement actions or other adverse consequences, and our business would be negatively affected. If we become subject to enforcement action by governmental regulatory agencies, our business would be negatively affected. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA or other governmental regulatory agencies, which enforcement actions may include the following: · untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties; · unanticipated expenditures to address or defend such actions; · issuance of form 483s, or other compliance or enforcement notices, communications, or correspondence from regulatory bodies; · recall, detention or seizure of our products; · operating restrictions or partial suspension or total shutdown of marketing, sales and production or offering of product- related services; · refusing or delaying our requests for 510 (k) clearance or de novo classification or PMA approval of new products or modified products; · requiring products that we determined to be classified and listed with the FDA as a Class I, 510 (k)- exempt medical device, or that we determined not to be a medical device and thus unregulated by the FDA, instead to be submitted for marketing authorization (510 (k) clearance, de novo classification, or PMA approval); · operating restrictions; · withdrawing market authorizations that have already been granted; · refusal to grant any export approval that might be required for our NOCISCAN product suite; or · criminal prosecution If any of these events were to occur, it would have a negative impact on our business, financial condition and results of operations. If certain of our medical device products cause or contribute to a death or a serious injury or malfunction in certain ways, we will

be required to report under applicable medical device reporting regulations, or MDRs, which can result in voluntary corrective actions or agency enforcement actions and harm our reputation, business, financial condition and results of operations. FDA's Medical Device Reporting ("MDR") regulation requires, medical device manufacturers to report to the FDA information of which the manufacturer becomes aware that a device has or may have caused or contributed to a death or serious injury or has malfunctioned in a way that would likely cause or contribute to death or serious injury if the malfunction of the device or a similar device marketed by the manufacturer were to recur. If we fail to report events required to be reported to the FDA within the required timeframes, or at all, the FDA could take enforcement action and impose sanctions against us. Any such adverse event involving our products also could result in the need to take corrective and preventative actions, such as changes to design or manufacturing processes, corrections, removals, or recalls or customer notifications, or agency action, such as inspection or enforcement action. Risk of harm to patients, including without limitation serious injury or death, associated with using our products could also result in product liability actions against us. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, would be costly, distract management from operating our business, could be used by competitors against us, and may harm our reputation, business, financial condition and results of operations. From time to time, we engage outside parties to perform services related to certain of our clinical studies. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to complete our clinical studies on our planned timelines, or at all, and may incur significant additional costs. The FDA's investigational device exemption ("IDE") regulations impose requirements on the conduct of certain clinical investigations conducted with medical devices. The requirements depend on whether the study is considered to be exempt, a nonsignificant risk or a significant risk. In general, clinical investigations with medical devices, including those that are IDE exempt, must comply with requirements for the protection of human subjects, which include review and approval by an institutional review board ("IRB") and informed consent of subject participants. Significant risk device studies also must submit an IDE to FDA for approval. The IDE regulations specify the responsibilities of sponsors and investigators to ensure compliance with IDE requirements, including compliance with Good Clinical Practice ("GCP") requirements. Failure to comply may result in FDA placing a temporary or permanent clinical hold on the study, issuance of warning letters, or other regulatory actions. From time to time, we engage consultants to help design, monitor and analyze the results of certain clinical studies and trials that we sponsor. The consultants we engage may interact with clinical investigators to enroll patients in our clinical studies. We depend on these consultants and clinical investigators to conduct clinical studies and trials and monitor and analyze data from these studies and trials under the investigational plan and protocol for the study or trial and in compliance with applicable regulations and standards. We may face delays in, or be prevented from, completing our clinical studies if these parties do not fulfill their obligations in a timely, compliant or competent manner. Such roles, functions, and related risks, also apply to certain employees of the Company. If these third parties or employees do not successfully carry out their duties, comply with Good Clinical Practice (GCP) guidelines and other applicable requirements, or meet expected deadlines, or if the quality, completeness or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical study protocols or for other reasons, our clinical studies or trials may need to be extended, delayed or terminated by us or be placed on clinical hold by FDA, or may otherwise prove to be unsuccessful, and we may have to conduct additional studies, which would significantly increase our costs. Healthcare reform initiatives and other administrative and legislative proposals may harm our business, financial condition, results of operations and cash flows in our key markets. There have been, and continue to be, proposals by the federal government, state governments, regulators and third-party payers to control or manage the increased costs of healthcare and, more generally, to reform the U. S. healthcare system. Certain of these proposals could limit the prices we are able to charge for our products or the coverage and reimbursement available for our products and could limit the acceptance and availability of our products. The adoption of proposals to control costs could harm our business, financial condition and results of operations. There likely will continue to be legislative and regulatory proposals at the federal and state levels directed at containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future or their full impact. The continuing efforts of the government, insurance companies, managed care organizations and other payers of healthcare services to contain or reduce costs of healthcare may harm: · our ability to set a price that we believe is fair for our products; · our ability to generate revenue and achieve or maintain profitability; and · the availability of capital. Recently there has been heightened governmental scrutiny over the manner in which companies set prices for their marketed products, which has resulted in several U. S. Congressional inquiries and proposed and enacted federal legislation designed to bring transparency to product pricing and reduce the cost of products and services under government healthcare programs. Additionally, individual states in the United States have also increasingly passed legislation and implemented regulations designed to control product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures. Moreover, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what products to purchase and which suppliers will be included in their healthcare programs. Adoption of price controls and other cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures may prevent or limit our ability to generate revenue and attain profitability. Various new healthcare reform proposals are emerging at the federal and state level. Any new federal and state healthcare initiatives that may be adopted could limit the amounts that federal and state governments will pay for healthcare products and services, and could harm our business, financial condition and results of operations. Our collection, use, storage, disclosure, transfer and other processing of sensitive and personal information could give rise to significant costs, liabilities and other risks, including as a result of investigations, inquiries, litigation, fines, legislative and regulatory action and negative press about our privacy and data protection practices, which may harm our business, financial conditions, results of operations and prospects. In the course of our operations, we collect, use, store, disclose, transfer and otherwise process an increasing volume of sensitive, and personal information including detailed recordings of MRI and MRS results from patients as well as information from our employees and third parties with

whom we conduct business. The collection, use, storage, disclosure, transfer and other processing of personal information is increasingly subject to a wide array of federal, state and foreign laws, rules, regulations, and standards regarding data privacy and security including comprehensive laws of broad application, such as the CCPA and the GDPR, that are intended to protect the privacy of personal information that is collected, used, stored, disclosed, transferred or otherwise processed in or from the governing jurisdiction. As we seek to expand our business, we are, and may increasingly become, subject to various laws, rules, regulations and standards, as well as contractual obligations, relating to data privacy and security in the jurisdictions in which we operate or in the jurisdictions where our patients may be. When conducting clinical studies, we face risks associated with collecting trial participants' data, especially health data, in a manner consistent with applicable laws and regulations, such as GCP guidelines or FDA human subject protection regulations. In many cases, these laws, rules, regulations and standards apply not only to third- party transactions, but also to transfers of information between or among us, any of our affiliates and other parties with whom we conduct business. These laws, rules, regulations and standards may be interpreted and applied differently over time and from jurisdiction to jurisdiction, and it is possible that they will be interpreted and applied in ways that may harm our business, financial condition and results of operations. The regulatory framework for data privacy and security worldwide is continuously evolving and developing and, as a result, interpretation and implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future. We are subject to many diverse laws and regulations relating to data privacy and security. In the United States, various federal and state regulators have adopted, or are considering adopting, laws and regulations concerning personal information and data security. Additionally, our customers may be subject to additional federal and state privacy and security laws, rules, regulations and standards, including HIPAA, that they may require us to comply with through contractual obligations. This patchwork of legislation and regulation may give rise to conflicts or differing views of personal privacy rights. For example, certain state laws may be more stringent or broader in scope, or offer greater individual rights, with respect to personal information than federal, foreign or other state laws, and such laws may differ from each other, all of which may complicate compliance efforts. Additionally, new privacy rules are being enacted in the United States and globally, and existing ones are being updated and strengthened. The CCPA regulates the processing of personal information of California residents and increases the privacy and security obligations of covered companies handling such personal information. The CCPA requires covered companies to, amongst other things, provide new and additional disclosures to California consumers and provide such consumers new data protection and privacy rights, including the ability to access their personal information and opt out of certain sales of personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for certain data breaches that result in the loss of personal information. This private right of action may increase the likelihood of, and risks associated with, data breach litigation. The CCPA was **last updated December 2024** ~~amended in September 2018 and November 2019~~, and it is possible that further amendments will be enacted, but even in its current form it remains unclear how various provisions of the CCPA will be interpreted and enforced. Moreover, a new privacy law, the California Privacy Rights Act, (" CPRA ") a consumer privacy ballot initiative that amends and expands the CCPA, ~~was recently passed~~ **took effect on January 1, 2023**. The CPRA affords California residents significantly more control over their personal information, imposes heightened compliance obligations on covered companies, and establishes a new enforcement agency dedicated to consumer privacy. ~~The CPRA's substantive provisions become effective January 1, 2023, and new regulations are expected to be introduced by July 1, 2022.~~ While aspects of the CPRA and its interpretation remain to be determined in practice, they create further uncertainty and may result in additional costs and expenses in an effort to comply. Further, all 50 states have passed laws regulating the actions that a business must take if it experiences a data breach, such as prompt disclosure to affected customers. In addition to data breach notification laws, some states have enacted statutes and rules requiring businesses to reasonably protect certain types of personal information they hold or to otherwise comply with certain specified data security requirements for personal information. We are also subject to the supervisory and enforcement authority of the Federal Trade Commission with regard to the collection, use, sharing, and disclosure of certain data collected from or about individuals. State laws are changing rapidly and there is discussion in Congress of a new federal data protection and privacy law to which we would become subject if it is enacted. All of these evolving compliance and operational requirements impose significant costs that are likely to increase over time, may require us to modify our data processing practices and policies, divert resources from other initiatives and projects, and could restrict the way products and services involving data are offered, all of which may harm our business, financial condition and results of operations. In the event we expand our operations internationally, we may become subject to additional foreign data privacy and security laws, rules, regulations, requirements, and standards, which in the European Union, for instance, have been significantly reformed. On May 25, 2018, the General Data Protection Regulation (" GDPR ") entered into force and became directly applicable in all European Union member states. The GDPR implements more stringent operational requirements than its predecessor legislation. For example, the GDPR requires companies to make more detailed disclosures to data subjects, requires disclosure of the legal basis on which companies can process personal data, makes it harder for companies to obtain valid consent for processing, requires the appointment of data protection officers when sensitive personal data, such as health data, is processed on a large scale, provides more robust rights for data subjects, introduces mandatory data breach notification through the European Union, imposes additional obligations on companies when contracting with service providers and requires companies to adopt appropriate privacy governance including policies, procedures, training and data audits. The GDPR permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to € 20 million or four percent of annual global revenues, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. If we become subject to the GDPR and do not comply with our obligations under the GDPR, we could be exposed to significant fines. Compliance with the GDPR will be a rigorous and time- intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties,

litigation, and reputational harm in connection with our European activities. In addition, we may be the subject of litigation or adverse publicity, which could negatively affect our business, financial condition and results of operations. We expect that there will continue to be new proposed laws and regulations concerning data privacy and security, and we cannot yet determine the impact such future laws, rules, regulations and standards may have on our business. New laws, amendments to or re-interpretations of existing laws, regulations, standards and other obligations may require us to incur additional costs and restrict our business operations. Because the interpretation, scope, and application of laws, regulations, standards and other obligations relating to data privacy and security are still uncertain, it is possible that these laws, regulations, standards and other obligations may be interpreted and applied in a manner that is inconsistent with our data processing practices and policies or the features of our products and services. If so, in addition to the possibility of fines, lawsuits, regulatory investigations, public censure, other claims and penalties, and significant costs for remediation and damage to our reputation, we could be materially and adversely affected if legislation or regulations are expanded to require changes in our data processing practices and policies or if governing jurisdictions interpret or implement their legislation or regulations in ways that negatively impact our business, financial condition and results of operations. We may be unable to make such changes and modifications in a commercially reasonable manner, or at all. In addition to government regulation, privacy advocates and industry groups have and may in the future propose self-regulatory standards from time to time. These and other industry standards may legally or contractually apply to us, or we may elect to comply with such standards. Any inability to adequately address data privacy or security-related concerns, even if unfounded, or to comply with applicable laws, regulations, standards and other obligations relating to data privacy and security, could result in additional cost and liability to us, harm our reputation and brand, damage our relationships with consumers and harm our business, financial condition and results of operations. We make public statements about our use and disclosure of personal information through our privacy policies, information provided on our website and press statements. Although we endeavor to comply with our public statements and documentation, we may at times fail to do so or be alleged to have failed to do so. The publication of our privacy policies and other statements that provide promises and assurances about data privacy and security can subject us to potential government or legal action if they are found to be deceptive, unfair or misrepresentative of our actual practices. Any concerns about our data privacy and security practices, even if unfounded, could damage the reputation of our business and harm our business, financial condition and results of operations. Complying with these numerous, complex and often changing laws, rules, regulations, and standards is expensive and difficult. Any failure or perceived failure by us or our service providers to comply with our posted privacy policies or with any applicable or potentially applicable federal or state laws, rules, regulations, standards, certifications or orders relating to data privacy, security or consumer protection, or any compromise of security that results in the theft, unauthorized access, acquisition, use, disclosure, or misappropriation of personal information or other user data, could result in significant fines or penalties, negative publicity or proceedings or litigation by governmental agencies or consumers, including class action privacy litigation in certain jurisdictions, which would subject us to significant awards, penalties or judgments, one or all of which could require us to change our business practices or increase our costs and could materially and adversely affect our business, financial condition and results of operations. In addition, if our practices are not consistent, or viewed as not consistent, with applicable legal and regulatory requirements, including changes in laws, regulations and standards or new interpretations or applications of existing laws, regulations and standards, we may also become subject to audits, inquiries, whistleblower complaints, adverse media coverage, investigations, criminal or civil sanctions, all of which may harm our business, financial condition and results of operations. Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could harm our business, financial condition and results of operations. We are exposed to the risk that our employees, independent contractors, consultants, commercial partners and vendors may engage in fraudulent or illegal activity. Misconduct by these parties could include intentional, reckless or negligent conduct or disclosure of unauthorized activities to us that violates: (i) the laws of the FDA and other similar state or 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, (iv) laws related to discrimination, harassment, or other conduct relating to a hostile work environment, or (v) 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 arrangements, discounting, marketing and promotion, structuring and commissions, certain customer incentive programs and other business arrangements generally. These laws also address the improper use of information obtained in the course of patient recruitment for clinical studies. We have adopted a code of conduct, employee handbook, and compliance policies, but 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, imprisonment, reporting and oversight obligations, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, 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. 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 integrity issues, or a negative impact to our reputation or brand. 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 harm our business, financial condition and results of operations. Significant disruptions in our information technology systems, whether through breaches or failures of our technology, unauthorized access or otherwise, may result in both an adverse impact to our products, as well as the unauthorized use, disclosure, modification or misappropriation of patient personal information, the occurrence of fraudulent activity, or other data security- related incidents, all of which could have a material and adverse impact on our business, financial condition and results of operations. We are increasingly dependent on complex information technology systems for the efficient functioning of our business, including the manufacture, distribution and maintenance of our products, as well as for accounting, data storage, compliance, purchasing and inventory management purposes. Further, our products collect, use, store, disclose, transfer, and otherwise process sensitive patient data, such as detailed recordings of MRIs to help clinicians make more informed treatment decisions and optimize their patients' care. These data are recorded by our technology and can be viewed by the physician during regular patient visits using the Physician Tablet or on demand through a secure website. We also collect, use, store, disclose, transfer, and otherwise process a growing volume of other personal information and confidential, proprietary and sensitive data, which may include procedure- based information and sensitive healthcare data, credit card, and other financial information, insurance information, and other potentially personally identifiable information. Our information technology systems or those of our service providers may be subject to computer viruses, phishing, social engineering, denial or degradation of service attacks, ransomware, malware attacks or other threats, cyberattacks, or dishonest acts by computer hackers or terrorists, failures during the process of upgrading or replacing software, databases or components thereof, power outages, damage or interruption from fires or other natural disasters, hardware failures, telecommunication failures and user errors, among other malfunctions. Technological interruptions or threats would disrupt our operations, including the ability of our clinicians to use our products as intended to treat patients, the ability of patients to safely and securely upload their data using and into our products, as well as our ability to adequately manufacture our products, timely ship and track product orders, project inventory requirements, manage our supply chain and otherwise adequately service our customers. Additionally, any of these incidents could result in the theft, unauthorized access, acquisition, use, disclosure, modification, or misappropriation of personal information of patients that use our products, trial participants, employees, third parties with whom we conduct business, as well as other confidential, proprietary, and sensitive data, and can also result in fraudulent activity, system disruptions or shutdowns. The occurrence of any actual or attempted breach, failure of security or fraudulent activity, the reporting of such an incident, whether accurate or not, or our failure to make adequate or timely disclosures to the public or law enforcement agencies following any such event, whether due to delayed discovery or a failure to follow existing protocols, could result in claims made against us or our service providers, which could result in state and / or federal litigation and related financial liabilities, as well as criminal penalties or civil liabilities, regulatory actions from state and / or federal governmental authorities, and significant fines, orders, sanctions, litigation and claims against us by consumers or third parties and related indemnification obligations. Actual or perceived security breaches or failures could also cause financial losses, increased costs, interruptions in the operations of our businesses, misappropriation of assets, significant damage to our brand and reputation with customers, patients, employees, and third parties with whom we do business, and result in adverse publicity, loss of consumer confidence, distraction to our management, and reduced sales and profits, any or all of which could harm our business, financial condition and results of operations. Our technology is also subject to compromise from internal threats, such as theft, misuse, unauthorized access or other improper actions by employees, service providers and other third parties with otherwise legitimate access to our systems and website. Data security- related incidents and fraudulent activity are increasing in frequency and evolving in nature. We rely on a framework of security processes, procedures, tools, and controls designed to protect our information and assets but, given the unpredictability of the timing, nature and scope of data security- related incidents and fraudulent activity, there can be no assurance that any security procedures and controls that we or our service providers have implemented will be sufficient to prevent data security- related incidents or other fraudulent activity from occurring. Furthermore, because the methods of attack and deception change frequently, are increasingly complex and sophisticated, and can originate from a wide variety of sources, including third parties such as service providers and even nation- state actors, despite our reasonable efforts to ensure the integrity of our systems and website, it is possible that we may not be able to anticipate, detect, appropriately react and respond to, or implement effective preventative measures against, all security breaches and failures and fraudulent activity. In the event we experience significant disruptions, we may be unable to repair our systems in an efficient and timely manner. We also face risks associated with security breaches affecting third parties with whom we are affiliated or otherwise conduct business. Due to applicable laws and regulations or contractual obligations, we may be held responsible for any breach, failure or fraudulent activity attributed to our service providers as they relate to the information we share with them. In addition, while we take precautions in selecting service providers, because we do not control our service providers and our ability to monitor their data security is limited, we cannot ensure the security measures they take will be sufficient to protect our information. Any of the foregoing could harm our business, financial condition and results of operations. As data security- related 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 information security vulnerabilities, or to protect against, respond to and recover from any potential, attempted, or existing security breaches. In addition, our remediation efforts may not be successful. The inability to implement, maintain and upgrade adequate safeguards could have a material and adverse impact on our business, financial condition and results of operations. Moreover, there could be public announcements regarding any data security- related incidents and any steps we take to respond to or remediate such incidents, and if securities analysts or investors perceive these announcements to be negative, it could, among other things, have a substantial adverse effect on the price of our common stock. Any of the foregoing could harm our business, financial condition and results of operations. We currently maintain a cybersecurity insurance policy and business interruption coverage in order to mitigate certain potential losses but this insurance is limited in amount, and we cannot be

certain that such potential losses will not exceed our policy limits, or will cover all potential claims to which we are exposed and may not be adequate to indemnify us for all liability that may be imposed. Therefore, failure to maintain or protect our information systems and data integrity effectively could harm our business, financial condition, and results of operations. We face potential liability related to the privacy of health information we obtain. We may maintain, use, and share sensitive health information that we receive directly from patients that use our technology, throughout the clinical study process, in the course of our research collaborations, and from healthcare providers in the course of using our products and systems. Most healthcare providers, including hospitals from which we obtain patient health information, are subject to privacy and security regulations promulgated under HIPAA, as amended by the HITECH, and also under GDPR. We believe that we are not currently classified or regulated under HIPAA or GDPR as a Covered Entity, but we believe we are considered and regulated as a Business Associate. Accordingly, we are subject to HIPAA and GDPR requirements or penalties as applied to Business Associates. However, in certain situations, any person may be prosecuted under HIPAA's criminal provisions either directly or under aiding- and- abetting or conspiracy principles. Consequently, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive, maintain, use, or transfer individually identifiable health information from a Covered Entity, as defined under HIPAA, that has not satisfied HIPAA's requirements for disclosure of individually identifiable health information. Furthermore, certain health privacy laws, data breach notification laws, consumer protection laws and genetic testing laws may apply directly to our operations or those of our collaborators and may impose restrictions on our collection, use and dissemination of individuals' health information. As such, we may be subject to state laws requiring notification of affected individuals and state regulators in the event of a breach of personal information, including certain health information, which is a broader class of information than the health information protected by HIPAA. To the extent we engage in clinical studies and commercial uses of our products outside the United States, we may implicate foreign data privacy and security laws and regulations, including the GDPR and legislation of the European Union member states implementing it. To the extent we do business in international markets now, and in the future, any failure by us or our third- party contractors to comply with the strict rules on the transfer of personal data from outside of the European Union, the United Kingdom, or other foreign country or territory into the United States in accordance with such laws and regulations may result in the imposition of criminal and administrative sanctions on such contractors, which could adversely affect our sales, business, financial condition, and results of operations. Moreover, patients about whom we or our contractors or collaborators obtain or share health information, as well as the providers who share this information with us or whom we share this data with, may have statutory or contractual rights that limit our ability to use and disclose the information. We may be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws. Potential claims alleging that we have violated individuals' privacy rights or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend and could result in adverse publicity that could negatively affect our business, financial condition and results of operations. If we or third- party contractors or consultants fail to comply with applicable federal, state or local regulatory requirements, we could be subject to a range of regulatory actions that could affect our or our contractors' ability to develop and commercialize our products and could harm or prevent sales of our technology, or could substantially increase the costs and expenses of developing, commercializing and marketing our products. Any threatened or actual government enforcement action could also generate adverse publicity and require that we devote substantial resources that could otherwise be used in other aspects of our business. Additionally, data collection, privacy and security have become the subject of increasing public concern and changing preferences towards data collection, privacy and security could adversely affect patient willingness to consent to our collection of their health information. Patients may be reluctant or unwilling to consent to the collecting of their health information, and patients that have opted- in to the collection of their health information may revoke their consent at any time, including as a result of these concerns or as a result of changes to our data policies that we have implemented or may implement in the future. In particular, the success of our business depends in part on our ability to lawfully obtain health information from our patients. If patients choose not to consent to the collection of their health information as a result of these concerns, or our customers who transfer patient data to us via the use of our products refuse to do so due to concerns for data privacy or potential related liabilities, or our consent or data privacy protection and management policies or practices are found to be unlawful, this could negatively impact the growth potential for our business. We have encountered potential customers in the EU who have been reluctant, and indeed refused, to become customers due to concerns about transferring of any private patient information from their practice in the EU into the United States. Certain such customers have indicated their opinion that such a transfer is, on its face, non- compliant with GDPR requirements due to certain rights of the US Federal Government to seize such data from US domiciled companies or storage facilities. We may need to expand our operations to host at least one foreign instance of our cloud- based post- processing software products within a foreign country, such as within the European Union, in order to overcome such concerns and reach and engage more customers to grow our business in the related territory. If we are unable to sufficiently dissuade these concerns held by certain potential customers outside of the United States, or do not establish certain changes in our private patient health information data privacy practices, such as moving the hosting of EU- based information to an EU- based instance of our products and storage of related patient health information we receive via use of our products, our sales, business, financial condition, and results of operations could be harmed. We could also encounter delays if a clinical study is suspended or terminated by us, by the IRBs or the Ethics Committees of institutions at which such studies are being conducted, by the Data Safety Monitoring Board for such trial or by the FDA or other regulatory authorities. Such authorities may suspend or terminate a clinical study due to a number of factors, including failure to conduct the clinical study in accordance with regulatory requirements, including GC. Risks related to our intellectual property If we are unable to obtain, maintain, protect, enforce and defend patents or other intellectual property protection for our technology, or if the scope of our patents and other intellectual property protections is not sufficiently broad, or as a result of our existing or any future out- licenses of our intellectual property, our competitors could develop and

commercialize products similar to or competitive with our products and services, our ability to continue to commercialize our technology, or our other products and services, may be harmed. As with other medical device companies, our success depends, in large part, on our ability to obtain, maintain, protect, enforce and defend a proprietary position for our products and services, which will depend upon our success in obtaining and maintaining effective patent and other intellectual property protection in the United States and other countries into which we may expand our business in the future that relate to our technology and any other products, their manufacturing processes and their intended methods of use. Furthermore, our success will also depend on our ability to enforce and defend those patents, as well as our other intellectual property. In some cases, we may not be able to obtain patents relating to our products and services which are sufficient to prevent third parties, such as our competitors, from copying and competing with other products or services that are the same, similar, or otherwise competitive with our products and services. Or, our competitors may have rights under current or future out-licenses of our intellectual property which could result in our competitors developing and commercializing products similar to or competitive with our products and services. Any failure to obtain, maintain, protect, enforce or defend patent and other intellectual property protection with respect to our NOCISCAN product suite and related services, or other aspects of our business, could harm our business, competitive position, financial condition and results of operations. Changes in the patent or other intellectual property laws, or their interpretation, in the United States and other countries may diminish our ability to protect our inventions or to obtain, maintain, protect, enforce, and defend our patents and other intellectual property rights, and could affect the value of our intellectual property or narrow the scope of our patents. Additionally, we cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors or other third parties. The patent prosecution process is expensive, time-consuming and complex and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patents or patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection in one, several, or all geographies. Although we enter into non-disclosure and confidentiality agreements with parties who have access to our confidential information or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, suppliers, consultants, advisors and other third parties, any of these parties may breach the agreements and publicly disclose such confidential information or research and development output. If such unauthorized public disclosure occurs before a patent application is filed, it could compromise or diminish our ability to seek patent protection. Such third parties could also breach obligations with respect to limited uses of our confidential information, which may include (i) breaching restrictions against making or inventing improvements or modifications to, or derivations of, our confidential technologies, and (ii) further separately applying, on their own behalf, for patent protections for such improvements, modifications, or derivations. Such breaches may compromise our ability to obtain or enforce our own patent protections for such improvements, modifications, or derivations. In addition, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our inventions and the prior art allow our inventions to be patentable over the prior art. Furthermore, the publication of discoveries in scientific literature often lags behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. As such, we cannot be certain that we were the first to make the inventions claimed in any of our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, relating to technology that we license from or license to third parties, including by way of our license from the Board of Regents of the University of California, and we are therefore reliant on our licensors or licensees. Therefore, these and any of our patents and patent applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Furthermore, our license agreements may be terminated by the licensor. Defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example, with respect to proper priority claims, inventorship and the like, although we are unaware of any such defects that we believe are of importance. If we or any of our current or future licensors or licensees fail to obtain, maintain, protect, enforce or defend such patents and other intellectual property rights, such rights may be reduced or eliminated. If any of our current or future licensors or licensees are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form, preparation or prosecution of our patents or patent applications, such patents or applications may be invalid and / or unenforceable. Any of these outcomes could impair our ability to prevent competition from third parties, which may harm our business. The strength of patent rights generally, and particularly the patent position of medical device companies, involves complex legal and scientific questions, can be uncertain, and has been the subject of much litigation in recent years. This uncertainty includes changes to the patent laws through either legislative action to change statutory patent law or court action that may reinterpret existing law or rules in ways affecting the scope or validity of issued patents. Our current or future patent applications may fail to result in issued patents in the United States or foreign countries with claims that cover our products, including our technology. Even if patents do successfully issue from our patent applications, third parties may challenge the validity, enforceability or scope of such patents, which may result in such patents being narrowed, invalidated or held unenforceable. Any successful challenge to our patents could deprive us of exclusive rights necessary for the successful commercialization of our products, including our NOCISCAN product suite. Furthermore, even if they are unchallenged, our patents may not adequately protect our technology or any other products we develop, provide exclusivity for these products or prevent others from designing around our claims. If the scope of any patent protection we obtain is not sufficiently broad, or if we lose any of our patent protection, our ability to prevent our competitors from commercializing similar or identical products could be adversely affected. If the breadth or strength of protection provided by the patents we hold or pursue with respect to our products is challenged, it could dissuade companies from collaborating with us to develop, or threaten our ability to commercialize, our technology. Patents have a limited

lifespan. In the United States, the natural expiration of a utility patent is generally 20 years after its effective filing date and the natural expiration of a design patent is generally 14 years after its issue date, unless the filing date occurred on or after May 13, 2015, in which case the natural expiration of a design patent is generally 15 years after its issue date. However, the actual protection afforded by a patent varies from country to country, and depends upon many factors, including the type of patent, the scope of its coverage, any terminal disclaimers filed or to be filed, overlap in claimed subject matter with other patents in the portfolio, the availability of regulatory- related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Without patent protection for our technology, we may be open to competition. Further, if we encounter delays in our development efforts, the period of time during which we could market our technology under patent protection would be reduced and, given the amount of time required for the development, testing and regulatory review of planned or future technology and products, patents protecting such technology and products might expire before or shortly after such products are commercialized. For information regarding the expiration dates of patents in our patent portfolio, see “ Business — Intellectual Property. ” Our U. S. issued patents are expected to expire between January 3, 2026 and March 15, 2033, without taking into account all possible patent term adjustments, extensions, or abandonments, and assuming payment of all appropriate maintenance, renewal, annuity, and other governmental fees. As our patents expire, the scope of our patent protection will be reduced, which may reduce or eliminate any competitive advantage afforded by our patent portfolio. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications licensed to us or assigned to us, currently or in the future, issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents assigned to us may be challenged, narrowed, circumvented or invalidated by third parties. Consequently, we do not know whether our NOCISCAN product suite or our other products will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative products in a non- infringing manner, which could harm our business, financial condition and results of operations. Some of our patents and patent applications may be co- owned or cross- licensed with third parties. If we give up, do not pursue, or are unable to obtain an exclusive license to any such third- party co- owners’ or licensee’ s interest in such patents or patent applications, such co- owners or cross- licensees may be able to license or sub- license, respectively, their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co- owners or co- licensees of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could harm our sales, business, financial condition and results of operations. We rely on a License from the Regents of the University of California, as well as other aspects of our own patented technology and intellectual property, in order to be able to use and sell various proprietary technologies that are material to our business, as well as technologies which we intend to use in our future commercial activities. Our rights to use these licensed technologies and the inventions claimed in the licensed patents, are subject to the continuation of, and our compliance with the terms of the license. The License provides that for so long as we pay patent prosecution costs, the Regents of the University of California will diligently prosecute and maintain the United States and foreign patents comprising the Patent Rights using counsel of its choice, and the UCSF Regents' counsel will take instructions only from The Regents of the University of California has the right to terminate the agreement upon advanced notice in the event of a default by us. The agreement will expire upon the expiration or abandonment of the last of the licensed patents. The patents subject to the agreement expire between 2025 and 2029. The loss of this license would materially negatively affect our ability to pursue our business objectives and result in material harm to our business operations. We may not be successful in obtaining or maintaining necessary rights to any products or processes we may have or develop through acquisitions and in- licenses. We may find it necessary or prudent to acquire, obtain, or maintain licenses to intellectual property or proprietary rights held by third parties that we may identify as necessary or important to our business operations. However, we may be unable to acquire, secure, or maintain such licenses to any intellectual property or proprietary rights from third parties that we identify as necessary for our technology or any future products we may develop. The acquisition or licensing of third- party intellectual property or proprietary rights is a competitive area, and our competitors may pursue strategies to acquire or license third party intellectual property or proprietary rights that we may consider attractive or necessary. Our competitors may have a competitive advantage over us due to their size, capital resources and greater 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 acquire or license third party intellectual property or proprietary rights on terms that would allow us to make an appropriate return on our investment or at all. We have an existing license with the Board of Regents of the University of California, and which covers multiple patents and patent applications for inventions that are incorporated into our products, and if we are unable to maintain this license, we may not be able to legally market or sell our current or future products, which would harm our sales, business, financial condition, and results of operations. If we are unable to successfully acquire or license third- party intellectual property or proprietary rights that we require for making, using, or selling our products or services, or to maintain the existing licenses to intellectual property rights we have, we may have to abandon the development, manufacturing, marketing, or selling of our related products that require those rights, which could harm our sales, business, financial condition, and results of operations. Patents directing to our technology could be found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad, which could harm our business, financial condition and results of operations. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. We may be subject to a third- party pre- issuance submission of prior art to the U. S. Patent and

Trademark Office (“USPTO”), or become involved in opposition, derivation, revocation, reexamination, post-grant and inter partes review, or IPR, or interference proceedings or other similar proceedings challenging our patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, such patent rights, allow third parties to commercialize our products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Moreover, we may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge our priority of invention or other features of patentability with respect to our patents and patent applications. Such challenges may result in loss of patent rights, in loss of exclusivity, or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical products or limit the duration of the patent protection of our products. Such proceedings also may result in substantial cost and require significant time from our management, even if the eventual outcome is favorable to us. In addition, if we initiate legal proceedings against a third party to enforce a patent relating to our products, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. 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 withheld relevant information from the USPTO, or made a false or misleading statement, or otherwise committed inequitable conduct, during prosecution. Defenses of these types of claims, regardless of their merit, would involve substantial litigation expense, would result in reputational harm, and would be a substantial diversion of employee resources from our business. Third parties may also raise claims challenging the validity or enforceability of our patents before administrative bodies in the United States or abroad, even outside the context of litigation, including through re-examination, post-grant review, IPR, interference proceedings, derivation proceedings and equivalent or similar proceedings in foreign jurisdictions (such as opposition proceedings). Such proceedings could result in the revocation of, cancellation of or amendment to our patents in such a way that they no longer relate to our products. The outcome for any particular patent following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. Moreover, potential third-party claims that are validated in a final ruling or determination regarding inequitable conduct with respect to securing or enforcing a patent could also potentially give rise to other adverse claims, which may include business torts or other causes of action regarding our enforcement of that patent, and could also potentially carry over and apply downstream to other patents that are related to (e.g. claim of priority) the instant patent. 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 potentially all, of the patent protection for the patents raised in such a claim. Such a loss of patent protection would harm our sales, business, financial condition, and results of operations. The medical device industry is characterized by patent litigation and in the future we could become subject to actual or threatened patent or other intellectual property litigation alleging our products or services infringe or misappropriate third party rights, which could be costly to address and defend, result in the diversion of management’s time and efforts, require us to pay damages, or prevent us from making, using, or selling our existing or future products. Patent litigation is prevalent in the medical device and diagnostic sectors. Our commercial success depends, in part, upon our ability and that of our suppliers to manufacture, market, sell, and use our proprietary technology without infringing, misappropriating or otherwise violating the intellectual property or proprietary rights of third parties. We may in the future become party to, or be threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our products. Third parties may assert infringement claims against us based on existing or future intellectual property rights, regardless of merit. If we are found to infringe a third party’s intellectual property rights, we could be required to incur costs to obtain a license from such third party to continue developing, making, using, or selling our products and services. We may also elect to enter into such a license in order to settle pending or threatened litigation. However, we may not be able to obtain any required license on commercially reasonable terms, or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies or methods licensed to us and could require us to pay significant royalties and other fees. We could be forced, including by court order, to cease commercializing the infringing product or service. In addition, we could be found liable for monetary damages, which may be significant. If we are found to have willfully infringed a third-party patent, we could be required to pay treble damages and attorneys’ fees. A finding of infringement could prevent us from commercializing our planned products in commercially important territories or force us to cease some of our business operations, which could harm our business and cause brand and reputational harm. An adverse infringement determination in one territory where such a claim might be brought could also potentially carry over to influence other similarly adverse claims being brought, and / or adverse results of those additional claims, in other territories where we have or seek a commercial presence. We could also be forced to redesign or otherwise change those products or services that use or implicate the allegedly infringing intellectual property, which could be costly, disruptive and infeasible. Many of our employees were previously employed at, and many of our current advisors and consultants are employed by, universities or other biotechnology, medical device, healthcare, or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, advisors and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we, or these employees, have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee’s former employer. Furthermore, although these agreements may be difficult to enforce, we may in the future be subject to claims that these individuals are violating non-compete agreements with their former employers. These and other claims that we have misappropriated the confidential information or trade secrets of third parties can have a similar negative impact on our business, including with respect to the infringement claims discussed

above. Even if we are successful in defending against intellectual property claims, litigation or other legal proceedings relating to such claims, the claims and related defense may still cause us to incur significant expenses, cause reputational harm, and could distract our technical and management personnel from their normal responsibilities. If we fail in defending any such claims, in addition to paying monetary damages or other settlements, we may lose valuable intellectual property rights or personnel, which could harm our business, financial condition and results of operations. We could potentially be required, or be forced or choose among other options, to negotiate a settlement of third party infringement claims that may include cross-licensing of our own patent or other intellectual property rights with the third party bringing the initial adverse claim against us. This could result in our inability to protect our products and services as exclusively proprietary only to us, and allow the third party to compete against us, with respect to the inventions or technologies related to those out-licensed rights, and which could also diminish the value of our products, services, and overall business and company, and harm our sales, business, financial condition, and results of operations. 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 negative impact on the price of our shares of common stock. Such litigation or proceedings could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of litigation or other intellectual property related proceedings could harm our business, financial condition and results of operations. Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements. Obtaining and maintaining our patent protection depends on compliance with various procedural measures, document submissions, fee payments and other requirements imposed by government 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 government fees on patents and patent applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our patents and applications. The USPTO and various non- U. S. government agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. In some cases, an intentional lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in the abandonment or lapse of the patent or patent application, resulting in a partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market with similar or identical products or technology, which could harm our business, financial condition and results of operations. Certain legal or contractual requirements, and / or rights of others involved in our development or products, may permit the U. S. government to disclose our confidential information to third parties. To the extent any of our current or future intellectual property is generated through the use of U. S. government funding, the provisions of the Bayh- Dole Act may similarly apply. For example, the National Institute of Health and the Regents of the University of California have limited rights to use certain of our patents and patent applications for research. Any exercise by the government of any of the foregoing rights could harm our business, financial condition, results of operations and prospects. If we fail to comply with our obligations in any current or future agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business. We are, and may become, party to license or collaboration agreements with third parties to advance our research or allow commercialization of our products. Such agreements may impose numerous obligations, such as development, diligence, payment, commercialization, funding, milestone, royalty, sublicensing, insurance, patent prosecution, enforcement and other obligations on us and may require us to meet development timelines, or to exercise certain efforts to develop and commercialize licensed products, in order to maintain the licenses. In spite of our best efforts, our licensors might conclude that we have materially breached such license agreements and might therefore terminate the license agreements, thereby removing or limiting our ability to develop and commercialize products and technologies covered by these license agreements. We have an existing license with the Regents of the University of California which covers multiple patents and patent applications for inventions that are incorporated into our products. Any termination of this or other licenses could result in the loss of significant rights and could harm our ability to commercialize our products and competitors or other third parties may have the freedom to seek regulatory approval of, and to market, products identical to ours, at least to the extent of products and services that incorporate the features captured by those previously licensed patent rights and assuming our licensor permits such competitive activities, either passively or via further out licensing, under their remaining patent rights. If we lose our licensed patent rights, we may also be required to cease our development and commercialization of certain of our products. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects. 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; · whether and the extent to which our technology and processes infringe, misappropriate or otherwise violate intellectual property rights of the licensor that are not subject to the license agreement; · our right to sublicense patent and other rights to third parties under collaborative development relationships; · our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our products, and what activities satisfy those diligence obligations; · the priority of invention of any patented technology; and · the ownership of inventions and know- how resulting from the joint creation or use of intellectual property by our future licensors and us and our partners. In addition, the agreements under which we may license intellectual property or technology from third parties are likely to be 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 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 sales, business, financial condition or results of operations. Moreover, if disputes over intellectual property that we may license prevent or impair our ability to maintain future license agreements on acceptable terms, we may be unable to successfully develop and commercialize the affected products, which could have a material adverse effect on our sales, business, financial conditions or results of operations. Our existing license with the Regents of the University of California, in particular, includes both exclusive rights, as applied to certain aspects of their patent rights under the license, and partial- exclusive and co- exclusive rights as applied to certain other aspects of the Licensor' s patent rights, under which we have rights for diagnostic- related patent claims. The balance of remaining rights for therapy- related claims are exclusively licensed to another third- party company. There are risks that the interpretation of which patent rights apply to us under our license, versus which patent rights apply to the other third- party company under their license, could be the subject of disagreement or dispute, the existence of which, and potential adverse result from which, could diminish the scope of rights we actually have. This could also be the subject of disagreement or dispute with respect to patent prosecution matters along the examination path of applications toward seeking issued patents. Any of the above could diminish, or prevent, our ability to commercialize all aspects of our products as intended, and which could result in harm to our sales, business, financial condition, or result of operations. Our existing license also includes exclusive rights to certain patents which are co- owned by us and the Board of Regents of the University of California, in relation to inventions that have been determined to be jointly invented by separate but joint inventors that are under different obligation of assignment to us and them. If we fail to maintain and / or lose those license rights to one or more of these co- owned patents and patent applications, others would have the ability to commercialize, or license the ability to commercialize, products or services covered by those patents competitively against us. This would result in us losing exclusive proprietary advantage with respect to technologies and methods relating to those patents, which could harm our sales, business, financial condition, and results of operations. If we are unable to obtain patent term extension under the Hatch- Waxman Amendments, our business may be materially harmed. Depending upon the timing, duration and specifics of FDA marketing approval of our products, one or more of the U. S. patents assigned or licensed to us may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch- Waxman Amendments. The Hatch- Waxman Amendments permit a patent restoration term of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. However, even if, at the relevant time, we have an issued patent covering our product, we may not be granted an extension if we were, for example, to fail to exercise due diligence during the testing phase or regulatory review process, to fail to apply within applicable deadlines or prior to expiration of relevant patents or otherwise to fail to satisfy applicable requirements. Moreover, the time period of the extension or the scope of patent protection afforded could be less than we request. Only one patent per approved product can be extended, the extension cannot extend the total patent term beyond 14 years from approval and only those claims covering the approved product, a method for using it or a method for manufacturing it may be extended. If we are unable to obtain patent term extension or restoration or the term of any such extension is less than we request, the period during which we can enforce our patent rights for the applicable product will be shortened and our competitors may obtain approval of competing products following our patent expiration. As a result, our ability to generate revenues could be adversely affected. Further, if this occurs, our competitors may take advantage of our investment in development and studies by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case. If we do not have adequate patent protection or other exclusivity for our products, our business, financial condition or results of operations could be adversely affected. We have limited foreign intellectual property rights and may not be able to protect our intellectual property and proprietary rights throughout the world, which could harm our business, financial condition and results of operations. We have limited intellectual property rights outside the United States. Filing, prosecuting and defending patents on our products in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but enforcement is not as strong as in the United States. While we do not currently operate or sell our products outside of the United States, these products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Patent protection must ultimately be sought on a country- by- country basis, which is an expensive and time- consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries, which may impede on our ability to grow outside of the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or

license. Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition and results of operations may be harmed. Changes in U. S. patent laws, or patent laws in other countries and jurisdictions, could diminish the value of patents in general, thereby impairing our ability to protect our products. Changes in either the patent laws or interpretation of the patent laws in the United States, or elsewhere, could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, generally the first to file a patent application was entitled to the patent. After March 2013, under the Leahy- Smith America Invents Act, or 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 will be entitled to the patent on an invention regardless of whether a third party, who may have filed a patent application later, was the first to actually invent the claimed invention. A third party that files a patent application in the USPTO after March 2013, but before we filed a patent application for the same invention (as defined by claims), could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we could continue incurring costs without being certain that we were the first to file any patent application related to our products or the first to invent any of the inventions claimed in our patents or patent applications. The America Invents Act also includes a number of significant changes that affect the way patent applications are prosecuted and also may affect patent litigation. These include allowing third- party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post- grant proceedings, including post- grant review, inter partes review and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U. S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Additionally, USPTO proceedings provide a venue for challenging the validity of patents at a cost must lower than district court litigation and on much faster timelines. This lower-cost, faster and potentially more potent tribunal for challenging patents could itself increase the likelihood that our own patents will be challenged. Therefore, 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. In addition, future actions by the U. S. Congress, the federal courts and the USPTO could cause the laws and regulations governing patents to change in unpredictable ways. Any of the foregoing could harm our business, financial condition and results of operations. In addition, recent 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 increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. For example, after the filing of our earlier filed patent applications, from which we have received granted patents and also continue to prosecute additional patent applications under priority filing claims, certain laws and interpretation of those laws changed. This includes, in particular, new changes that diminish or make it more difficult to obtain, enforce, or defend as valid, claims related to medical diagnostics, any methods, and in particular any methods involving the human body or medical procedures. Our patent portfolio is principally related to medical diagnostic methods, which in many cases merge these multiple areas of patent laws that have since been changed. Some of our patents were issued prior to certain such changes in the laws occurring, which could potentially result in certain risks that the patents which were initially valid when granted, under the laws at that time, had become invalid due to the later changes in the laws. Moreover, some of our patents were granted after these changes in the laws, but these may still be subject to risk of challenge due to uncertainty in interpreting and applying these newer changes in the laws related to medical diagnostic methods to our issued patent claims. Depending on future actions by the U. S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. We cannot predict how this and future decisions laws or regulations by the courts, the U. S. Congress or the USPTO may impact the value of our patents. Any similar adverse changes in the patent laws of other jurisdictions could also harm our business, financial condition, results of operations and prospects. We may be subject to claims, including third- party claims of intellectual property infringement, misappropriation or other violations against us or our collaborators, challenging the ownership or inventorship of our intellectual property and, if unsuccessful in any of these proceedings, we may be required to obtain licenses from third parties, which may not be available on commercially reasonable terms, or at all, or to cease the development, manufacture and commercialization of one or more of our products. The medical device industry is highly competitive and dynamic. Due to the focused research and development that is taking place by several companies, including us and our competitors in this field, the intellectual property landscape is in flux and it may remain uncertain in the future. As such, we may be subject to claims that current or former employees, collaborators or other third parties have an interest, either as an owner, co- owner, or otherwise, in our patents, trade secrets or other intellectual property as an inventor or co- inventor. Additionally, we could become subject to significant intellectual property- related litigation and proceedings relating to our or third- party intellectual property and proprietary rights. For example, we may have inventorship disputes arise from conflicting

obligations of employees, consultants or others who are involved in developing our products, or could face third- party claims of intellectual property infringement, misappropriation or other violations, including by a licensor from whom we' ve licensed certain intellectual property. These risks apply to our existing license from the Regents of the University of California, both in relation to patent rights we co- own with them as a result of joint invention between our and their respective inventors, and in relation to co- existent license rights that we share with another third- party company in some of those patent rights, as further summarized above. Litigation may be necessary to defend against these and other claims challenging inventorship of our patents, trade secrets or other intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our products. If we were to lose exclusive ownership of such intellectual property, other owners may be able to license their rights to other third parties, including our competitors. We also may be required to obtain and maintain licenses from third parties, including parties involved in any such disputes. 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 and commercialization of one or more of our products. The loss of exclusivity or the narrowing of our patent claims could limit our ability to stop others from using or commercializing similar or identical technology and products. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could harm our business, financial condition and results of operations. Additionally, our commercial success depends, in part, on our and any potential future collaborators' ability to develop, manufacture, market and sell any products that we may develop and use our proprietary technologies without infringing, misappropriating or otherwise violating the patents and other intellectual property or proprietary rights of third parties. It is uncertain whether the issuance of any third- party patent would require us or any potential collaborators to alter our development or commercial strategies, obtain licenses or cease certain activities. The medical device industry is characterized by extensive litigation regarding patents and other intellectual property rights, as well as administrative proceedings for challenging patents, including interference, inter partes or post- grant review, derivation and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. Third parties, including our competitors, may currently have patents or obtain patents in the future and claim that the manufacture, use or sale of our products infringes upon these patents. We have not conducted an extensive search of patents issued or assigned to other parties, including our competitors, and no assurance can be given that patents containing claims relating to our products, parts of our products, technology or methods do not exist, have not been filed or could not be filed or issued. In addition, because patent applications can take many years to issue and because publication schedules for pending patent applications vary by jurisdiction, there may be applications now pending of which we are unaware and which may result in issued patents which our current or future products infringe. Also, because the claims of published patent applications can change between publication and patent grant, there may be published patent applications that may ultimately issue with claims that we infringe. Unintentionally abandoned patents or applications can also be revived, so there may be recently revived patents or applications of which we are unaware. As the number of competitors in our market grows and the number of patents issued in this area increases, the possibility of patent infringement claims against us escalates. Moreover, we may face claims from non- practicing entities, or NPEs, which have no relevant product revenue and against whom our own patent portfolio may have no deterrent effect. Third parties may in the future claim that our products infringe or violate their patents or other intellectual property rights. Defense of infringement claims, regardless of their merit or outcome, would involve substantial litigation expense and would be a substantial diversion of management and other employee resources from our business, and may impact our reputation. In the event of a successful claim of infringement against us, we may be enjoined from further developing or commercializing the infringing products and / or have to pay substantial damages for use of the asserted intellectual property, including treble damages and attorneys' fees were we found to willfully infringe such intellectual property. Claims that we have misappropriated the confidential information or trade secrets of third parties could harm our business, financial condition and results of operations. We also might have to redesign any our allegedly infringing products or technologies, which may be impossible or require substantial time and monetary expenditure. Engaging in litigation, including defending against third- party infringement claims is very expensive, particularly for a company of our size, and time- consuming. 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 negative impact on our common stock price. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of litigation or administrative proceedings more effectively than we can because of greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings against us could impair our ability to compete in the marketplace. The occurrence of any of the foregoing could harm our business, financial condition and results of operations. We may become involved in lawsuits to protect or enforce our patents and other intellectual property rights, which could be expensive, time- consuming and unsuccessful. Competitors may infringe our patents, or the patents of any current or future licensing partners, or we may be required to defend against claims of infringement. Our ability to enforce our patent rights against competitors who infringe our patents depends on our ability to detect such infringement. It may be difficult to detect infringers who do not advertise the components or processes that are used in their products or services. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor' s or potential competitor' s product. For example, many of our patents relate to methods and related computer processing architectures and structures for post- processing data. The use of these methods and structures may not be obvious or certain to assess, and may not be possible or at least may be challenging to reveal or confirm by reverse engineering, based on limited evidence that might be available to

us, such as for example from only being able to observe the results of using those methods or architectures. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded if we were to prevail may not be commercially meaningful. In addition, our patents or the patents of our licensing partners also may become involved in inventorship, priority or validity disputes. For example, although we try to ensure that our employees, consultants and advisors are not in breach of any past contractual obligations and do not use the proprietary information or know-how of others in the work that they do for us, we may in the future become subject to claims that we or these individuals have, inadvertently or otherwise, used or disclosed intellectual property, including trade secrets or other proprietary information, of their former university or employer. Additionally, we may be subject to claims from third parties challenging intellectual property rights we regard as our own, based on claims that our agreements with employees or consultants obligating them to assign intellectual property to us are ineffective or in conflict with prior or competing contractual obligations to assign inventions to a previous employer, or to another person or entity. Furthermore, while it is our policy to require all employees and contractors to execute agreements assigning relevant intellectual property to us, we may also be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. These assignment agreements may not be self-executing or adequate in scope, and may be breached or challenged, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. We may not have adequate remedies for any such breaches, and such claims could harm our business, financial condition and results of operations. To counter or defend against such claims can be expensive and time-consuming, and it may be necessary, or we may desire to, enter into a license to settle any such claims; however, there can be no assurance that we would be able to obtain a license on commercially reasonable terms, if at all. In an infringement proceeding, a court may decide that our patent is invalid or unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover such technology. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. 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 litigation. Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our management and other personnel from their normal responsibilities. 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 negative impact on our common stock price. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors 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. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could harm our ability to compete in the marketplace, including the ability to hire new employees or contract with independent sales representatives. Additionally, we may lose valuable intellectual property rights or personnel. Any of the foregoing could harm our business, financial condition and results of operations. If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be harmed. Our registered and unregistered trademarks or trade names may be challenged, infringed, circumvented, declared generic or determined to be violating or infringing on marks held by others. We may not be able to protect our rights to these trademarks and trade names, which we need to build or sustain name recognition among potential partners, customers and patients in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to continue to build brand identity and possibly leading to market confusion. In fact, a practice exists with international scope, and which may become manifest in a given case in any or only certain territories, in which certain third parties will deliberately secure or allege they own trademarks or tradenames that are specifically being first used by another party in order to extort license fees or damages in those territories in which the original user of the mark had not filed or perfected its rights to the mark. In addition, there could be potential trade name or trademark infringement, or dilution claims brought by owners of other trademarks. Over the long term, if we are unable to establish name recognition based on our trademarks, trade names, domain names or other intellectual property, then we may not be able to compete effectively, and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names or other intellectual property may be ineffective, could result in substantial costs, diversion of resources, or adverse impact to our brand and could harm our sales, business, financial condition, and results of operations. Intellectual property rights do not necessarily address all potential threats, and limitations in intellectual property rights could harm our business, financial condition and results of operations. The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, may evolve, 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 our products or utilize similar technology but that are not covered by the claims of our patents or that incorporate certain technology in our products that is in the public domain;
- our intellectual property strategy may be limited, we may not seek protection for intellectual property that may ultimately become relevant to our business, or our invention disclosure process may prove insufficient to encourage inventors to come forward with protectable intellectual property;
- we, or our current or future licensors or collaborators, might not have been the first to make the inventions related to the applicable issued patent or pending patent application assigned or licensed to us now or in the future;
- we, or our current or future licensors or collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- we, or our current or future licensors or collaborators, may fail to meet our obligations to the U. S. government regarding any future patents and patent applications funded by U. S. government grants, leading to the loss or unenforceability of patent rights;
- others may

independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights; · it is possible that our current or future pending patent applications will not lead to issued patents; · it is possible that there are prior public disclosures that could invalidate our patents, or parts of our patents; · it is possible that there are unpublished applications or patent applications maintained in secrecy that may later issue with claims related to our products or technology similar to ours; · it is possible that our patents or patent applications omit individuals that should be listed as inventors or include individuals that should not be listed as inventors, which may cause these patents or patents issuing from these patent applications to be held invalid or unenforceable; · issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties; · the claims of our patents or patent applications, if and when issued, may not cover our products or technologies; · the laws of foreign countries may not protect our proprietary rights or the rights of current or future licensors or collaborators to the same extent as the laws of the United States; · the inventors of our patents or patent applications may become involved with competitors, develop products or processes that design around our patents, or become hostile to us or the patents or patent applications on which they are named as inventors; · our competitors or other third parties 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 have engaged in scientific collaborations in the past and will continue to do so in the future and our collaborators may develop adjacent or competing products that are outside the scope of our patents; · we may not develop additional proprietary technologies that are patentable; · our trade secrets may be misappropriated, without an ability to know or reverse engineer the misappropriation, or we may lose trade secret protections based on a failure to properly establish or maintain them; · certain employees, consultants, or other collaborators may be engaged on terms that do not prevent them from inventing improvements, modifications, alterations, derivations of our technologies and methods, or otherwise from inventing alternative or new technologies or methods and pursuing them outside of and competitive with the company; · the patents of others may harm our business; or · we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property, and thereby potentially preventing us from continuing to use those related technologies or practice those related methods. Any of the foregoing could harm our business, financial condition and results of operations. If we are unable to protect the confidentiality of our other proprietary information, our business and competitive position may be harmed. In addition to patent protection, we also rely on other proprietary rights, including protection of trade secrets, know-how and other confidential or proprietary information that is not patentable or that we elect not to patent. However, such information can be difficult to protect, and some courts, for instance, are less willing or unwilling to protect trade secrets. To maintain the confidentiality of our trade secrets and proprietary information, we rely heavily on confidentiality provisions that we have in contracts with our employees, consultants, collaborators, suppliers, customers, and others upon the commencement of their relationship with us. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. Furthermore, we may not be able to prevent the unauthorized disclosure or use of our technical knowledge or other trade secrets by such third parties, despite the existence generally of these confidentiality restrictions. These contracts may not provide meaningful protection or equitable remedies for our trade secrets, know-how, or other proprietary information in the event of any unauthorized use, misappropriation, or disclosure of such trade secrets, know-how, or other proprietary information. There can be no assurance that such third parties will not breach their agreements with us, that we will have adequate remedies for any breach, or that our trade secrets will not otherwise become known or independently developed by competitors. Despite the protections we do place on our intellectual property or other proprietary rights, monitoring unauthorized use and disclosure of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property or other proprietary rights have or will be adequate. Trade secret violations are often a matter of state law, and the criteria for protection of trade secrets can vary among different jurisdictions. In addition, the laws of many foreign countries will not protect our intellectual property or other proprietary rights to the same extent as the laws of the United States. Consequently, we may be unable to prevent our proprietary technology from being exploited abroad, which could affect our ability to expand to foreign markets or require costly efforts to protect our products. We also license rights to use certain proprietary information and technology from third parties. The use of such proprietary information and technology is therefore subject to the obligations of the applicable license agreement between us and the owner. For example, the software we developed for our technology includes the use of open source software that is subject to the terms and conditions of the applicable open source software licenses that grant us permission to use such software. The owner of any such proprietary information or technology also might not enforce or otherwise protect its rights in the proprietary information or technology with the same vigilance that we would, which would allow competitors to use such proprietary information and technology without having to adhere to a license agreement with the owner. To the extent our intellectual property or other proprietary information protection is incomplete, we are exposed to a greater risk of direct competition. A third party could, without authorization, copy or otherwise obtain and use our products or technology, or develop similar products or technology. Our competitors could purchase our products and attempt to reverse engineer or replicate some or all of the competitive advantages we derive from our development efforts or design around our protected products or technology. Our failure to secure, protect and enforce our intellectual property rights could substantially harm the value of our products, brand and business. The theft or unauthorized use or publication of our trade secrets and other confidential business information could reduce the differentiation of our products, substantially and adversely impact our sales and commercial operations and harm our business. Additionally, the value of our investment in development or business acquisitions could be reduced and third parties might make claims against us related to losses of their confidential or proprietary information. Any of the foregoing could materially and adversely affect our business, financial condition and results of operations. Further, it is possible that others will independently develop the same or similar technology or product or otherwise obtain access to our unpatented technology, and in such cases, we could not assert any trade secret rights against such

parties. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our trade secret rights and related confidentiality and nondisclosure provisions. If we fail to obtain or maintain trade secret protection, or if our competitors otherwise obtain our trade secrets or independently develop technology or products similar to and potentially competing with our products, our competitive market position could be materially and adversely affected. In addition, some courts are less willing or unwilling to protect trade secrets and agreement terms that address non-competition are difficult to enforce in many jurisdictions and might not be enforceable in certain cases. We also seek to preserve the integrity and confidentiality of our data and other confidential information by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations, systems and tools, agreements or security measures may be breached, whereby detecting the disclosure or misappropriation of confidential information and enforcing a claim that a party illegally disclosed or misappropriated confidential information is difficult, expensive and time-consuming, and the outcome is unpredictable. Further, we may not be able to obtain adequate remedies for any breach. Our inability to use software licensed from third parties, or our use of open-source software under license terms that interfere with our proprietary rights, could disrupt our business. Our products, including our technology and methods used, include the use of open-source software that is subject to the terms and conditions of the applicable open-source software licenses that grant us permission to use such software. Although we monitor our use of open-source software, the terms of many open source licenses to which we are subject have not been interpreted by U. S. or foreign courts, and there is a risk that such licenses could be construed in a manner that imposes unanticipated conditions or restrictions on our ability to provide our technology to our customers. Moreover, we cannot ensure that we have not incorporated additional open-source software in our products in a manner that is inconsistent with the terms of the applicable license or our current policies and procedures. In the future, we could be required to seek licenses from third parties in order to continue offering our solutions, which licenses may not be available on terms that are acceptable to us, or at all. Claims related to our use of open-source software could also result in litigation, require us to purchase costly licenses or require us to devote additional research and development resources to change the software underlying our technology, any of which would have a negative effect on our business, financial condition and operating results and may not be possible in a timely manner. We and our customers may also be subject to suits by parties claiming infringement due to the reliance by our products on certain open source software, and such litigation could be costly for us to defend or subject us to injunctions enjoining us from the sale of our products that contain open source software. Alternatively, we may need to re-engineer our products or discontinue using portions of the functionality provided by our products. In addition, the terms of open source software licenses may require us to provide software that we develop using such software to others on unfavorable terms, such as by precluding us from charging license fees, requiring us to disclose our source code, requiring us to license certain of our own source code under the terms of the applicable open source license or requiring us to provide notice on our products using such code. Any such restriction on the use of our own software, or our inability to use open source or third-party software, could result in disruptions to our business or operations, or delays in our development of future products or enhancements of our existing products, such as our RNS System, which could impair our business. Other risks facing our company If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit or halt the marketing and sale of our technology. The expense and potential unavailability of insurance coverage for liabilities resulting from our technology could harm our business and our ability to sell our technology. We face an inherent risk of product liability as a result of the marketing and sale of our technology. Although we have established internal procedures designed to minimize risks that may arise from quality issues, there can be no assurance that we will eliminate or mitigate occurrences of these issues and associated liabilities. Our products and services are diagnostic in nature and involve an exam that is non-invasive using other third-party MR scanner products and technologies. Those exams are also conducted by other third party MR service providers. The results of using our products are also intended to provide information to doctors that help them perform a diagnosis for their patient, using all other diagnostic information that is available to them. The downstream results from those diagnoses may also lead to certain treatments being performed, which are decided upon between that treating doctor and the patient (and related payers), and which are conducted by that treating doctor on the patient. We are not responsible for the performance of those MR scanners, nor for the performance of the MR service providers for conducting those patient exams using the MR scanners, nor for the final diagnosis performed by a doctor as assisted via the results of our products in combination with other available information, nor for the decisions and performance on conducting treatments or other on-going patient care, or the patient outcomes from that care, following the use of our diagnostic assistance product. However, there are risks that certain liability exposures or claims could be threatened or actually filed against us with respect to the performance or results of these other activities around and relating to, but not directly caused by, the use of our products, including with respect to the use of our products in the overall patient care regimen that might result in adverse patient outcomes. Even if we successfully defend any such allegation or claim, this could involve significant risk of liability exposure and significant cost and diversion of resources and focus. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit or halt commercialization of our products. Regardless of the merits or eventual outcome, liability claims may result in: · decreased demand for our technology; · injury to our brand or reputation; · initiation of investigations by regulators; · costs to defend the related litigation; · increased insurance premiums; · a diversion of management's time and our resources; · substantial monetary awards to trial participants or patients; · regulatory investigations, product recalls, withdrawals or labeling, marketing or promotional restrictions; · loss of revenue; · exhaustion of any available insurance and our capital resources; and · the inability to market and sell our products. We believe we have adequate product liability insurance, but it may not prove to be adequate to cover all liabilities that we may incur. Insurance coverage is increasingly expensive. We currently carry product liability insurance in the amount of \$ 5 million in the aggregate. In the future, we may not be able to maintain or obtain insurance at a reasonable cost or in an amount adequate to satisfy any liability that may arise. Our insurance policy contains various exclusions, and we may be subject to a product

liability claim for which we have no coverage. The potential inability to obtain sufficient product liability insurance at an acceptable cost to protect against product liability claims could prevent or inhibit the marketing and sale of products we may develop. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts, which would harm our business, financial condition and results of operations. In addition, any product liability claims brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing continuing coverage, harm our patient- focused brand, negatively impact our reputation in the industry, significantly increase our expenses and reduce product sales. Some of our customers may also have difficulty in procuring or maintaining liability insurance to cover their operations, including their use of our products. Medical malpractice carriers are withdrawing coverage in certain states or substantially increasing premiums. If this trend continues or worsens, our customers may discontinue using our products and potential additional customers may opt against purchasing our products due to the cost or inability to procure insurance coverage. The failure of third parties to meet their contractual, regulatory and other obligations could adversely affect our business. We rely on licensors, suppliers, vendors, partners, consultants, and other third parties to research, develop, and partake in both the commercialization of our technology, as well as manage certain parts of our business. Using these third parties poses a number of risks, such as: · they may not perform to our standards or legal requirements; · they may not produce reliable results; · they may not perform in a timely manner; · they may not maintain confidentiality of our proprietary information; · disputes may arise with respect to ownership of rights to products developed with our partners; and · disagreements could cause delays in, or termination of, the research, development or commercialization of our products or result in litigation or arbitration. If and as any of one or more of these identified parties might be replaced in the future by another party with whom we might engage or rely upon for similar technological or business purposes, or to the extent we may expand our business to involve and rely on still more additional parties for similar purposes as those listed (e. g. additional MR scanner vendors), similar risks would apply to those other parties. Moreover, some third parties may be located in markets subject to political and social risk, corruption, infrastructure problems and natural disasters, in addition to country- specific privacy and data security risk given current legal and regulatory environments. Failure of third parties to meet their contractual, regulatory and other obligations may materially affect our business. Litigation and other legal proceedings may harm our business. From time to time in the future we may become involved in legal proceedings relating to patent and other intellectual property matters, product liability claims, employee matters, tort or contract claims, federal regulatory investigations, private rights of action, securities class action and other legal proceedings or investigations, which could have a negative impact on our reputation, business and financial condition and divert the attention of our management from the operation of our business. Litigation is inherently unpredictable and can result in excessive or unanticipated verdicts, judgements, and / or injunctive relief that affect how we operate our business. We could incur judgments or enter into settlements of claims for monetary damages or for agreements to change the way we operate our business, or both. There may be an increase in the scope of these or other matters or there may be additional lawsuits, claims, proceedings, or investigations in the future, which could harm our business, financial condition and results of operations. Adverse publicity about regulatory or legal action against us, irrespective of outcome, could damage our reputation and brand image, undermine our customers' confidence, and reduce long- term demand for our products, even if the regulatory or legal action is unfounded or not material to our operations. Our operating results may fluctuate across periods, 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 across periods, which makes it difficult for us to predict our future operating results. Accordingly, the results of any one quarter or period should not be relied upon as an indication of future performance. Our quarterly and annual operating results may fluctuate due to a variety of factors, many of which are outside of our control, including, but not limited to: · The level of demand for our technology and any future technology, which may vary significantly from period to period; · Expenditures that we may incur to acquire, develop or commercialize additional technology; · The timing and cost of obtaining regulatory approvals or clearances to expand our indications and get future approvals of any future technology or features; · Pricing pressures; · Our ability to expand the geographic reach of our commercial efforts; · The degree of competition in our industry and any change in the competitive landscape of our industry, including consolidation among our competitors or future partners; · Coverage and reimbursement policies with respect to our technology, and potential future technology that compete with our products; · The timing and success or failure of preclinical or clinical studies for expanding the indications of our technology or any future technology we develop or competing technology; · Positive or negative coverage in the media or clinical publications of our technology or technology of our competitors or our industry; · The timing and cost of, and level of investment in, research, development, licenses, regulatory approval, commercialization activities, acquisitions and other strategic transactions, or other significant events relating to our technology, which may change from time to time; · The cost of developing our technology, which may vary depending on the terms of our agreements with third- party; and · Future accounting pronouncements or changes in our accounting policies. The cumulative effects of these factors could result in 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. Further, our historical results are not necessarily indicative of results expected for any future period, and quarterly results are not necessarily indicative of the results to be expected for the full year or any other period. Investors should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, it could harm our business, financial condition, and results or operations. We will incur increased costs as a result of operating as a public company, and our management and board of directors will be required to devote substantial time to compliance with our public company responsibilities and corporate governance practices. As a public company, we will incur significant legal, accounting,

and other expenses that we did not incur as a private company. We expect such expenses to further increase after we are no longer an emerging growth company. The Sarbanes- Oxley Act, the Dodd- Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq Capital Market, and other applicable securities rules and regulations impose various requirements on public companies. Furthermore, most senior members of our management team as well as our board of directors do not have significant experience with operating a public company. As a result, our management, board of directors, and other personnel will have to devote a substantial amount of time to compliance with these requirements. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time- consuming and costly. We cannot predict or estimate the amount of additional costs we will incur as a public company or the timing of such costs.

Risks related to the ownership of our common stock and IPO Warrants Our stock price may be volatile, and the value of our common stock and IPO Warrants may decline. The market price of our common stock and IPO Warrants may be highly volatile and may fluctuate or decline substantially as a result of a variety of factors, some of which are beyond our control or are related in complex ways, including:

- Actual or anticipated fluctuations in our financial condition and results of operations;
- Variance in our financial performance from expectations of securities analysts or investors;
- Changes in the coverage decisions, reimbursement or pricing of our technology;
- Changes in our projected operating and financial results;
- Changes in laws or regulations applicable to our technology;
- Announcements by us or our competitors of significant business developments, acquisitions, or new offerings;
- Publicity associated with issues related to our technology;
- Our involvement in regulatory investigations or litigation;
- Future sales of our common stock or other securities, by us or our stockholders, as well as the anticipation of lock- up releases;
- Changes in senior management or key personnel;
- The trading volume of our common stock;
- Changes in the anticipated future size and growth rate of our market;
- General economic, regulatory, and market conditions, including economic recessions or slowdowns;
- Changes in the structure of healthcare payment systems; and
- Developments or disputes concerning our intellectual property or other proprietary rights.

Broad market and industry fluctuations, as well as general economic, political, regulatory, and market conditions, may negatively impact the market price of our common stock. In addition, given the relatively small expected public float of shares of our common stock on the Nasdaq Capital Market, the trading market for our shares may be subject to increased volatility. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us, because medical device companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management’ s attention and resources, which could harm our reputation and our business. A significant portion of our total outstanding shares may be sold into the market, which could cause the market price of our common stock to drop significantly, even if our business is performing well. Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. You may experience additional dilution if any of our outstanding common stock warrants are exercised. If the holders of any of our outstanding common stock warrants exercise their warrants, you will experience dilution at the time they exercise their warrants.

~~The issuance of common stock to White Lion pursuant to the Equity Line Purchase Agreement may cause substantial dilution to our existing shareholders, and the sale of such shares acquired by White Lion could cause the price of our common stock to decline. Under our Equity Line Purchase Agreement with White Lion, the Company has the right, but not the obligation to require White Lion to purchase, from time to time, up to of \$ 10, 000, 000 in aggregate gross purchase price of newly issued shares of the Company’ s common stock. Through March 1, 2024, the Company has sold 750, 000 shares to White Lion for total proceeds of \$ 2, 912, 481. After White Lion has acquired shares under the Equity Line Purchase Agreement, it may sell all, some or none of those shares. Sales to White Lion by us pursuant to the Equity Line Purchase Agreement under this prospectus may result in substantial dilution to the interests of other holders of our common stock. The sale of a substantial number of shares to White Lion, or anticipation of such sales, could make it more difficult for us to sell equity or equity- related securities in the future at a time and at a price that we might otherwise desire. The number of shares of our common stock ultimately offered for resale by White Lion is dependent upon the number of shares of common stock issued to the White Lion pursuant to the Equity Line Purchase Agreement. Depending on a variety of factors, including market liquidity of our common stock, the issuance of shares to the Selling Securityholder may cause the trading price of our common stock to decline.~~

The price of our common stock and IPO Warrants may be volatile and fluctuate substantially, which could result in substantial losses for investors in our common stock. Our common stock price is likely to be volatile. The stock market in general and the market for bio- technology companies in particular, has experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your common stock at or above your investment price. The market price for our common stock may be influenced by many factors, including:

- the success of competitive products or technologies;
- regulatory or legal developments in the United States,
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates, and our commercialization efforts;
- actual or anticipated changes in our development timelines;
- our ability to raise additional capital;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our product candidates;
- significant lawsuits, including patent or stockholder litigation;
- variations in our financial results or those of companies that are perceived to be similar to us;
- general economic, industry and market conditions; and
- the other factors described in this “ Risk Factors ” section.

If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance. In the past, following periods of volatility in the market price of a company’ s securities, securities class- action litigation often has been instituted against that company. Such litigation, if instituted against us, could cause us to incur substantial costs to defend

such claims and divert management's attention and resources. Because we do not expect to pay dividends in the foreseeable future, investors seeking cash dividends should not purchase shares of our common stock. We have never declared or paid any cash dividends on our common stock. We currently intend to retain future earnings, if any, to finance the expansion of our business. As a result, we do not anticipate paying any cash dividends in the foreseeable future. Our payment of any future dividends will be at the discretion of our Board of Directors after taking into account various factors, including but not limited to our financial condition, operating results, cash needs, growth plans and the terms of any credit agreements that we may be a party to at the time. Accordingly, investors seeking cash dividends should not purchase our shares. If securities analysts do not publish research or reports about our business or if they publish negative evaluations of our stock, the price of our stock could decline. The trading market for our common stock will rely, in part, on the research and reports that industry or financial analysts publish about us or our business. We do not currently have, and may never obtain, research coverage by industry or financial analysts. If no, or few, analysts commence coverage of us, the trading price of our stock would likely decrease. Even if we do obtain analyst coverage, if one or more of the analysts covering our business downgrade their evaluations of our stock, the price of our stock could decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price to decline. We are an emerging growth company and a smaller reporting company, and our compliance with the reduced reporting and disclosure requirements applicable to emerging growth companies and smaller reporting companies could make our common stock and IPO Warrants less attractive to investors. We are an emerging growth company, as defined in the JOBS Act, and we expect to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including the auditor attestation requirements of Section 404, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved and extended adoption period for accounting pronouncements. Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company," which would allow us to continue to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in this prospectus and our periodic reports and proxy statements. We cannot predict whether investors will find our common stock less attractive as a result of our reliance on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We will remain an emerging growth company until the earliest of (i) the end of the fiscal year following the fifth anniversary of the completion of our IPO, (ii) the first fiscal year after our annual gross revenues exceed \$ 1.235 billion, (iii) the date on which we have, during the immediately preceding three-year period, issued more than \$ 1.00 billion in non-convertible debt securities, or (iv) the end of any fiscal year in which the market value of our common stock held by non-affiliates exceeds \$ 700 million as of the end of the second quarter of that fiscal year. Provisions in our corporate charter and our bylaws and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management. The anti-takeover provisions of the Delaware General Corporation Law (the "DGCL") may discourage, delay or prevent a change in control by prohibiting us from engaging in a business combination with an interested stockholder for a period of three years after the person becomes an interested stockholder, even if a change in control would be beneficial to our existing stockholders. Provisions in our corporate charter and our bylaws discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions also could limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions: · allow the authorized number of our directors to be changed only by resolution of our board of directors; · limit the manner in which stockholders can remove directors from the board; · establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors; · require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent; · limit who may call stockholder meetings; and · authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a stockholder rights plan, or so-called "poison pill," that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors. Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the DGCL, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware or, under certain circumstances, the federal district courts of the United States of America will be the exclusive forums for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, employees or agents. Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware (or, if the Court of Chancery of the State of Delaware lacks subject matter jurisdiction, any state court located within the State of Delaware or, if all such state courts lack subject matter jurisdiction, the federal district court for the District of Delaware) is the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law for: · any derivative action or proceeding brought on our behalf; · any action asserting a breach of fiduciary duty; · any action arising pursuant to the Delaware General

Corporation Law, our amended and restated certificate of incorporation, or our amended and restated bylaws; and any action asserting a claim against us that is governed by the internal-affairs doctrine. These provisions would not apply to suits brought to enforce a duty or liability created by the Exchange Act or any claim for which the federal district courts of the United States of America have exclusive jurisdiction. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. Our stockholders cannot waive compliance with the federal securities laws and the rules and regulations thereunder. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock will be deemed to have notice of, and consented to, the provisions of our amended and restated certificate of incorporation described in the preceding sentences. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of provides that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such an instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such actions in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions. These exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers, and other employees. If a court were to find either exclusive-forum provision in our amended and restated certificate of incorporation in effect upon the effectiveness of our IPO to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving the dispute in other jurisdictions, all of which could harm our business and financial condition. Item 1B Unresolved Staff Comments