Risk Factors Comparison 2024-03-28 to 2023-03-30 Form: 10-K

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Investing in our common stock involves a high degree of risk. These risks include, but are not limited to, those described below, each of which may be relevant to an investment decision. You should carefully consider the risks described below, together with all of the other information in this Annual Report on Form 10- K, including our financial statements and related notes and Item 7. " Management' s Discussion and Analysis of Financial Condition and Results of Operations. " before deciding to invest in our common stock. The realization of any of these risks could have a significant adverse effect on our reputation, business, financial condition, results of operations and growth, and our ability to accomplish our strategic objectives. In that event, the market price of our common stock could decline, and you may lose part or all of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations and the market value of our common stock. Risks Related to Our Financial Position and Need for Additional Capital We have incurred significant operating losses since inception, we expect to incur operating losses in the future and we may not be able to achieve or sustain profitability. We have limited history operating as a commercial company. We have incurred net losses since our inception and expect to continue to incur losses for the foreseeable future. For the years ended December 31, ~~2022~~ **2023** and December 31, ~~2021~~ **2022** , we had net losses of $ **14, 247, 124 and $** 11, 394, 170 ~~and $ 7, 537, 845~~ , respectively. As of December 31, ~~2022~~ **2023** , we had an accumulated deficit of $ ~~94~~ **108** , ~~134~~ **381** , ~~505~~ **629** . Based on our current operating plan, our current cash and cash equivalents and revenue are expected to be sufficient to fund our ongoing operations into the ~~first quarter~~ **second half** of ~~2024~~ **2025** . Our estimate as to how long we expect our existing cash and cash equivalents and revenue to be able to continue to fund our operations is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate **, and we may need** ~~. We do not expect liquidity~~ to **seek additional funds sooner than planned** ~~be sufficient for twelve months from the date of these financial statements~~ . To date, we have financed our operations primarily through our initial public offering, private placements of our **common and** convertible preferred stock, ~~and amounts borrowed~~ **sales of common stock** under ~~a credit facility~~ **an at- the market- agreement and convertible notes and warrants** . We have devoted substantially all of our resources to development activities related to our FemBloc system and FemaSeed product, including research and development and clinical and regulatory initiatives. We expect that our operating expenses will continue to increase as we continue to build our infrastructure, develop, enhance and commercialize new products and incur additional operational costs associated with being a public company. As a result, we expect to continue to incur operating losses for the foreseeable future and may never achieve profitability. Furthermore, even if we do achieve profitability, we may not be able to sustain or increase profitability on an ongoing basis. If we do not achieve or sustain profitability, it will be more difficult for us to finance our business and accomplish our strategic objectives, either of which would have a material adverse effect on our business, financial condition and results of operations and cause the market price of our common stock to decline. In addition, failure of our FemBloc ~~and FemaSeed solutions~~ **solution** to be approved to market ~~or granted de novo classification, respectively~~ , or to significantly penetrate existing or new markets **with our products** would negatively affect our business, financial condition, and results of operations. We need substantial additional funding and may be unable to raise capital when needed, which could force us to delay or reduce our commercialization efforts or product development programs. Based on our current operating plan, our current cash, cash equivalents and revenue are expected to be sufficient to fund our ongoing operations into the ~~first quarter~~ **second half** of ~~2024~~ **2025** . However, we have based these estimates on assumptions that may prove to be incorrect, and we could spend our available financial resources much faster than we currently expect. Any future funding requirements will depend on many factors, including: • The initiation, scope, rate of enrollment, progress, success, and cost of our current or future clinical trials; • The cost of our research and development activities; • The acceptance of our clinical trial data by the FDA or foreign regulatory authorities; • Patient, physician and market acceptance of our **intrauterine artificial insemination product and** permanent birth control system ~~, intrauterine artificial insemination product and~~ women- specific medical product solutions; • The cost of filing and prosecuting patent applications and defending and enforcing our patent or other intellectual property rights; • The cost of defending, in litigation or otherwise, any claims that we infringe third- party patents or other intellectual property rights; • The cost and timing of additional regulatory clearances, de novo grants or approvals; • The cost and timing of establishing additional sales and marketing capabilities; • Costs associated with any product recall that may occur; • The effect of competing technological and market developments; • The extent to which we acquire or invest in products, technologies and businesses, although we currently have no commitments or agreements relating to any of these types of transactions; and • The costs of operating as a public company. Any additional equity or debt financing that we raise may contain terms that are not favorable to us or our stockholders. If we raise additional funds by selling additional shares of our common stock or other securities convertible into or exercisable or exchangeable for shares of our common stock, the issuance of such securities will result in dilution to our stockholders. Furthermore, investors purchasing any securities we may issue in the future may have rights superior to the rights of our common stockholders. In addition, any future debt financing into which we enter may impose upon us covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, repurchase our common stock, make certain investments and engage in certain merger, consolidation or asset sale transactions. If we raise additional funds through collaboration and licensing arrangements with third- parties, it may be necessary to relinquish some rights to our technologies or our products, or grant licenses on terms that are not favorable to us. Furthermore, we cannot be certain that

additional funding will be available on acceptable terms, if at all. If we do not have, or are not able to obtain, sufficient funds, we may have to delay development or commercialization of our products or license to third- parties the rights to commercialize products or technologies that we would otherwise seek to commercialize. We also may have to reduce ~~marketing~~ **commercialization efforts** , customer support or other resources devoted to our products or cease operations. Any of these factors could harm our business, financial condition, and results of operations ~~. There is substantial doubt about our ability to continue as a going concern. As a result of our current limited financial liquidity, we have concluded that substantial doubt exists about our ability to continue as a going concern. If we are unable to raise sufficient capital when needed, our business, financial condition and results of operations will be materially and adversely affected, and we will need to significantly modify our operational plans to continue as a going concern. If we are unable to continue as a going concern, we may have to liquidate our assets, and the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our financial statements. Our lack of cash resources and our potential inability to continue as a going concern may materially adversely affect our share price and our ability to raise new capital, enter into critical contractual relations with third parties and otherwise execute our development strategy~ . Our financial results may fluctuate significantly and may not fully reflect the underlying performance of our business. Our quarterly and annual results of operations may vary significantly in the future, and period- to- period comparisons of our operating results may not be meaningful. Accordingly, the results of any one quarter or period should not be relied upon as an indication of future performance. Our quarterly and annual financial results may fluctuate as a result of a variety of factors, many of which are outside our control and, as a result, may not fully reflect the underlying performance of our business. One such factor includes seasonal variations of sales. We may in the future experience higher sales in the fourth quarter as a result of patients having paid their annual insurance deductibles in full, thereby reducing their out- of- pocket costs. Other factors that may cause fluctuations in our quarterly and annual results include: • Patient and physician adoption of our FemBloc system, if approved to market; • Patient and physician adoption of our FemaSeed product ~~, if granted de novo classification~~ ; • Changes in coverage policies by third- party payors that affect the reimbursement of procedures using our products; • Unanticipated pricing pressure; • The hiring, retention and continued productivity of sales representatives; • Our ability to expand the geographic reach of our sales and marketing efforts; • Our ability to obtain regulatory clearance or approval for any products in development or for our current products for additional indications or in additional countries outside the United States; • Results of clinical research and trials on our existing products and products in development; • Delays in receipt of anticipated purchase orders; • Delays in, or failure of, component and raw material deliveries by our suppliers; and • Positive or negative coverage in the media or clinical publications of our products or products of our competitors or our industry. Because our quarterly and annual results may fluctuate, period- to- period comparisons may not be the best indication of the underlying results of our business and should only be relied upon as one factor in determining how our business is performing. These fluctuations may also increase the likelihood that we will not meet our forecasted performance, which could negatively affect the market price for our common stock. Our ability to use our net operating losses and research and development credit carryforwards to offset future taxable income may be subject to certain limitations. In general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an " ownership change, " generally defined as a more than 50 percentage points increase in ownership by value in its equity ownership by certain shareholders over their lowest ownership percentage within a rolling three- year period, is subject to limitations on its ability to utilize its pre-change net operating losses, or NOLs, and its research and development credit carryforwards to offset future taxable income. Certain substantial changes in our ownership between February 2004 **to date** ~~and June 2021~~ will more likely than not limit our ability to utilize the amount of our existing NOLs and research and development credit carryforwards, and if we undergo any further ownership change, our ability to utilize NOLs and research and development credit carryforwards could be further limited by Sections 382 and 383 of the Code. In addition, our ability to deduct net interest expense may be limited if we have insufficient taxable income for the year during which the interest is incurred, and any carryovers of such disallowed interest would be subject to the limitation rules similar to those applicable to NOLs and other attributes. Future changes in our stock ownership, some of which might be beyond our control, could result in an ownership change under Section 382 of the Code. For these reasons, in the event we experience a change of control, we may not be able to utilize a material portion of the NOLs, research and development credit carryforwards or disallowed interest expense carryovers, even if we attain profitability. Risks Related to Discovery and Development Enrollment and retention of subjects in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control. We may encounter delays or difficulties in enrolling, or be unable to enroll, a sufficient number of subjects to complete any of our clinical trials on our current timelines, or at all, and even once enrolled, we may be unable to retain a sufficient number of subjects to complete any of our trials. For example, as a result of the COVID- 19 pandemic, we have had slower than expected site initiation and subject enrollment for our clinical trials due to subject and staff rescheduling, lack of available site staff and turnover and longer timelines to train staff at new sites. Slow site initiation and subject enrollment in our clinical trials has led to delays in our development timelines and may cause further delays in the future. Subject enrollment in clinical trials and completion of subject follow- up depend on many factors, including the size of the subject population, the nature of the trial protocol, the proximity of subjects to clinical sites, the eligibility criteria for the clinical trial, subject compliance, competing clinical trials and clinicians' and' subjects' perceptions as to the potential advantages of the product being studied in relation to other available therapies, including any new treatments that may be approved for the indications we are investigating. For example, subjects may be discouraged from enrolling in our clinical trials if the trial protocol requires them to undergo extensive post- treatment procedures or follow- up to assess the safety and effectiveness of a product candidate, or they may be persuaded to participate in contemporaneous clinical trials of a competitor' s product candidate. In addition, patients participating in our clinical trials may drop out before completion of the trial or experience adverse medical events unrelated to our products. Delays in subject enrollment or failure of subjects to continue to participate in a clinical trial may delay commencement or completion

of the clinical trial, cause an increase in the costs of the clinical trial and delays, or result in the failure of the clinical trial. Delays or failures in planned site initiation and / or subject enrollment or retention may result in increased costs, program delays or both, which could have a harmful effect on our ability to develop our product candidates or could render further development impossible. In addition, we rely on clinical trial sites to ensure timely conduct of our clinical trials and, while we have entered into agreements governing their services, we are limited in our ability to compel their actual performance. ~~Extenuating circumstances at clinical trial sites may result in a slowdown in enrollment due to consolidation activities and the aftermath of the overturn of Roe v Wade. It has been reported that there have been over 25 transactions since the start of 2021 in the infertility market, which is rapidly evolving into large commercial entities. This rapidly changing market dynamics may be disruptive to the practice and affect the conduct of clinical studies as integration occurs. The American Society of Reproductive Medicine (ASRM) issued a statement March 17, 2023 on the abortion policy proposals affecting reproductive medicine. ASRM stated, " At the crux of the issue many of the proposals to ban or otherwise limit access to abortion care fail to protect the use of assisted reproductive technologies, including IVF, and so- called " personhood " measures (defining life as beginning at conception or fertilization) are multiplying across the nation, causing alarm bells to sound for medical practitioners and infertility patients alike. Such proposals could, intentionally or not, limit and even ban the use of IVF and routine, safe, and medically proven procedures, such as the removal of an embryo that fails to implant in a uterus, or the disposal of unused embryos. " This uncertainty may affect subject enrollment in clinical studies being conducted at facilities providing infertility services. The FDA may not allow us to initiate a pivotal trial for FemBloc PMA approval due to safety concerns. During the conduct of our studies for FemBloc and ultrasound confirmation with the FemChec device, misinterpretation of the ultrasound test was observed and confirmed by an independent clinical events committee that resulted in a higher- than expected number of pregnancies in the clinical trials. Enrollment was paused for the pivotal trial and subjects are continuing to be followed for safety through 5 years. We completed enrollment in a small IDE study (stage II validation study) to evaluate the adequacy of certain proposed mitigations and validate the ultrasound confirmation test in September 2022. The study data from this stage II validation study will be used to support which of the two confirmation tests (ultrasound or radiology) should be studied in a new pivotal trial to support a potential future application for Premarket Approval (PMA) for FemBloc. We cannot be certain that FDA will permit us to initiate a new pivotal clinical study.~~ Our current product candidates are in various stages of development. Our product candidates may fail in development or suffer delays that adversely affect their commercial viability. If we fail to obtain or maintain FDA approval to market and sell our FemBloc ~~, or a granted de novo classification of FemaSeed, or if such approval or de novo classification is delayed,~~ our business will be materially harmed. The process of seeking regulatory approval, the grant of a de novo classification, or 510 (k) clearance to market a medical device is expensive and time consuming. There can be no assurance that approval, de novo classification, or 510 (k) clearance will be granted. If we are not successful in obtaining timely approval of our FemBloc system ~~or de novo classification of FemaSeed product from the FDA~~ , we may never be able to generate significant revenue and may be forced to cease operations ~~. In the future, we will seek an IDE approval to conduct a clinical trial of the FemBloc system for female permanent birth control to support a subsequent PMA application, and we will also be submitting a request for de novo classification of the FemaSeed product for artificial insemination~~ . The FDA approval process requires an applicant to demonstrate the safety and effectiveness based, in part, on extensive data, including, but not limited to, technical, preclinical, clinical trial, manufacturing and labeling data. The de novo classification process requires an applicant to demonstrate that general controls, or general and special controls, are sufficient to provide reasonable assurance of safety and effectiveness and that the probable benefits of the device outweigh the probable risks. The de novo request is supported by performance data, which may include clinical data. The FDA can delay, limit or deny approval of a device for many reasons, including: • We may not be able to demonstrate to the FDA' s satisfaction that our product is safe and effective for its intended use; • The FDA may disagree that our clinical data supports the label and use that we are seeking; • The FDA may disagree that the data from our preclinical studies and clinical trials is sufficient to support marketing authorization; and • The manufacturing process and facilities we use may not meet applicable requirements. Obtaining approval, clearance or granted de novo classification from the FDA or any foreign regulatory authority could result in unexpected and significant costs for us and consume management' s time and other resources. The FDA could ask us to supplement our submissions, collect additional non- clinical data, conduct additional clinical trials, prepare additional manufacturing data or information or engage in other time- consuming actions, or it could simply deny our applications. In addition, if approved or granted approval to market, we will be required to obtain additional FDA approvals or clearances prior to making certain modification to our devices, and the FDA may revoke the approval or clearance or impose other restrictions if post- market data demonstrates safety issues or lack of effectiveness. If we are unable to obtain and maintain the necessary regulatory approvals and clearances to market our products, our financial condition may be adversely affected, and our ability to grow domestically and internationally would likely be limited. Additionally, even if approved ~~or granted de novo classification~~ , FemBloc ~~or FemaSeed~~ may not be approved ~~or a de novo classification request may not be granted~~ for the indications that are necessary or desirable for successful commercialization or profitability. **As we evolve from a company that is primarily involved in clinical development to a company that is also involved in commercialization, we may encounter difficulties in expanding our operations successfully. With the FDA clearance of FemaSeed, we will need to expand our development, regulatory, manufacturing, and marketing and sales capabilities and may need to further contract with third parties to provide these capabilities, such as collaborators, distributors, marketers and additional suppliers. We currently have limited experience as a company in or infrastructure for sales, marketing and distribution, and our operations have historically been limited primarily to clinical development activities. We intend to establish a sales organization with technical expertise and supporting distribution capabilities to commercialize FemaSeed. This will be expensive and time-consuming. In addition, we may not be able to hire a sales force that is sufficient in size or has adequate expertise in the medical markets that we target. Any failure or delay in the development of our internal sales, marketing and distribution**

capabilities would adversely affect the commercialization of FemaSeed and other products and product candidates. Maintaining third- party relationships for these purposes will impose significant added responsibilities on members of our management and other personnel. We must be able to effectively manage our development efforts, recruit and train sales and marketing personnel, effectively manage our participation in the clinical studies in which our product candidate and any future product candidates are involved and improve our managerial, development, operational and finance systems, all of which may impose a strain on our administrative and operational infrastructure. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our products. We are ~~substantially~~ **significantly** dependent on the FDA' s permission to market our FemBloc system ~~and FemaSeed product~~, as well as market acceptance in the United States for ~~them~~ **it**, and our failure to receive FDA authorization to market ~~either~~ the FemBloc system or ~~FemaSeed product or~~ the failure of ~~them~~ **it** to gain such market acceptance would negatively impact our business. Since our inception, we have devoted ~~substantially all~~ **a significant amount** of our efforts to the development of our intrauterine delivery technology that is the basis for our FemBloc system ~~and FemaSeed product~~. We have not yet received authorization from the FDA to market and sell ~~either~~ the FemBloc system ~~nor the FemaSeed product~~ in the United States. However, we will incur costs, including costs to build our sales force **for commercialization of our other products**, in anticipation of FDA authorization to market ~~these~~ **this** ~~systems~~ **system. Since the target service providers for our FDA- cleared FemaSeed product is different than what we anticipate for our FemBloc system, the sales force we are currently building for our FemaSeed product will not be able to be used for the FemBloc system, and we will need to maintain and support multiple commercialization efforts simultaneously if we are able to market both products, if we obtain authorization for FemBloc**. If we are unable to obtain authorization from the FDA to market and sell ~~these~~ **this** ~~systems~~ **system** in the United States and then to achieve significant market acceptance in the United States, our results of operations will be adversely affected as the United States is expected to be the principal market for ~~these~~ **this** ~~products~~ **product**. Further, because we have incurred costs prospectively in advance of FDA authorization, we would be unable to recoup these costs if the product ~~candidates~~ **candidate** ~~are~~ **is** not authorized for marketing by the FDA. We have other commercial products ~~and others in development~~, but their revenue is currently minimal, thus, if we are unsuccessful in commercializing the FemBloc system or ~~FemaSeed product or~~ are unable to market the FemBloc system ~~or FemaSeed product~~ as a result of a quality problem, failure to maintain or obtain regulatory marketing authorizations, unexpected or serious complications or other unforeseen negative effects related to ~~these~~ **this** ~~systems~~ **system** or the other factors discussed in these risk factors, we would lose an additional source of revenue, and our business will be materially adversely affected. The clinical development process required to obtain regulatory approvals is lengthy and expensive with uncertain outcomes, and our data developed in those clinical trials is subject to interpretation by FDA and foreign regulatory authorities. If clinical trials of our ~~current~~ FemBloc system ~~, FemaSeed product~~ and future products do not produce results necessary to support regulatory approval, a granted de novo classification or clearance in the United States or, with respect to our current or future ~~products~~ **product candidates**, elsewhere, we will be unable to commercialize these products and may incur additional costs or experience delays in completing, or ultimately be unable to complete, the commercialization of those products. We are currently seeking PMA approval for our permanent birth control ~~solution and the granting of a de novo classification for our artificial insemination~~ solution. In order to obtain PMA approval for the FemBloc system, we must conduct well- controlled clinical trials designed to assess the safety and effectiveness of the product candidate. ~~A de novo classification request must also include data demonstrating the benefits and risks of the device and FDA is requiring clinical data on the FemaSeed product.~~ Conducting clinical trials is a complex and expensive process, can take many years, and outcomes are inherently uncertain. We incur substantial expense for, and devote significant time to, clinical trials but cannot be certain that the trials will ever result in commercial revenue. We may experience significant setbacks in clinical trials, even after earlier clinical trials showed promising results, and failure can occur at any time during the clinical development process. Any of our products may malfunction or may produce undesirable adverse effects that could cause us, institutional review boards ~~,~~ or IRBs, or regulatory authorities to interrupt, delay or halt clinical trials. We, IRBs, the FDA, or another regulatory authority may suspend or terminate clinical trials at any time to avoid exposing trial participants to unacceptable health risks. Successful results of preclinical studies are not necessarily indicative of future clinical trial results, and predecessor clinical trial results may not be replicated in subsequent clinical trials. Moreover, interim results or topline results may be subject to change upon full review of the data from a clinical trial. Additionally, **the** FDA' s approval of an IDE application permits initiation of the clinical study described in the IDE application but does not mean that FDA agrees that the study design is appropriate or that the results of the study will be sufficient to obtain marketing authorization (i. e., PMA approval, 510 (k) clearance, or grant of a de novo request). The FDA may disagree with our interpretation of the data from our preclinical studies and clinical trials, or may find the clinical trial design, conduct or results inadequate to prove safety or effectiveness, and may require us to pursue additional preclinical studies or clinical trials, which could further delay the clearance, de novo classification, or approval of our products. The data we collect from our preclinical studies and clinical trials may not be sufficient to support FDA approval, a request for de novo classification, or clearance, and if we are unable to demonstrate the safety and effectiveness of our future products in our clinical trials, we will be unable to obtain regulatory approval, a granted de novo classification, or clearance to market our products. In addition, we may estimate and publicly announce the anticipated timing of the accomplishment of various clinical, regulatory and other product development goals, which are often referred to as milestones. These milestones could include the submission to the FDA of an IDE application to commence a clinical trial for a new product candidate; the enrollment of patients in clinical trials; the release of data from clinical trials; and other clinical and regulatory events; and the obtainment of the right to affix the CE mark in the European Union. The actual timing of these milestones could vary dramatically compared to our estimates, in some cases for reasons beyond our control. We cannot assure you that we will meet our projected milestones and if we do not meet these milestones as publicly announced, the commercialization of our products may be delayed and, as a result, our stock

price may decline. Clinical trials are necessary to support PMA applications, certain de novo classification requests, and certain 510 (k) premarket notifications and may be necessary to support PMA supplements or subsequent 510 (k) submissions for modified versions of our marketed devices. This would require the enrollment of large numbers of suitable subjects, which may be difficult to identify, recruit and maintain as participants in the clinical trial. The earlier clinical studies ~~supporting~~ **involved 228 subjects and supported** the IDE for the new pivotal trial, which will be the basis for the PMA application for our FemBloc system ~~, involved 228 subjects~~ . Adverse outcomes in the IDE approved pivotal trial or post- approval studies could also result in restrictions or withdrawal of approval of the PMA. We will likely need to conduct additional clinical trials in the future for the approval of the use of our products in some foreign countries. Clinical testing is difficult to design and implement, can take many years, can be expensive and carries uncertain outcomes. The initiation and completion of any of these studies may be prevented, delayed, or halted for numerous reasons. We may experience a number of events during the conduct of our clinical trials that could adversely affect the costs, timing or successful completion, including: • We are required to submit an IDE application to **the** FDA, which must become effective prior to commencing human clinical trials, and **the** FDA may reject our IDE application and notify us that we may not begin investigational trials; • Regulators and other comparable foreign regulatory authorities may disagree as to the design or implementation of our clinical trials; • Regulators and / or IRBs or other reviewing bodies may not authorize us or our investigators to commence a clinical trial, or to conduct or continue a clinical trial at a prospective or specific trial site; • We may not reach agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites; • Clinical trials may produce negative or inconclusive results, or we may not agree with regulatory authorities on the interpretation of our clinical trial results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs; • The number of subjects or patients required for clinical trials may be larger than we anticipate, enrollment in these clinical trials may be insufficient or slower than we anticipate, and the number of clinical trials being conducted at any given time may be high and result in fewer available patients for any given clinical trial, or patients may drop out of these clinical trials at a higher rate than we anticipate; • Our third- party contractors, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all; • We might have to suspend or terminate clinical trials for various reasons, including a finding that the subjects are being exposed to unacceptable health risks; • We may have to amend clinical trial protocols or conduct additional studies to reflect changes in regulatory requirements or guidance, which we may be required to submit to an IRB and / or regulatory authorities for reexamination; • Regulators, IRBs, or other parties may require or recommend that we or our investigators suspend or terminate clinical research for various reasons, including safety signals or noncompliance with regulatory requirements; • The cost of clinical trials may be greater than we anticipate; • Clinical sites may not adhere to the clinical protocol or may drop out of a clinical trial; • We may be unable to recruit a sufficient number of clinical trial sites or trial subjects; • Regulators, IRBs, or other reviewing bodies may fail to approve or subsequently find fault with our • Manufacturing processes for clinical and commercial supplies, the supply of devices or other materials necessary to conduct clinical trials may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply; • Approval policies or regulations of FDA or applicable foreign regulatory authorities may change in a manner rendering our clinical data insufficient for approval; and • Our current or future products may have undesirable side effects or other unexpected characteristics. Clinical trials must be conducted in accordance with the laws and regulations of the FDA and other applicable regulatory authorities' legal requirements, regulations or guidelines, and are subject to oversight by these governmental agencies and IRBs at the medical institutions where the clinical trials are conducted. We have in the past and may in the future have to terminate a clinical trial site which is found through our clinical trial monitoring activities to be noncompliant with our clinical trial protocols or with applicable laws, regulations, requirements and guidelines for the conduct of our clinical trials. In addition, clinical trials must be conducted with supplies of our devices produced in conformance with design control requirements in 21 CFR § 820. 30 and stored and used by clinical trial sites in accordance with our clinical trial protocols. Furthermore, we rely on clinical trial sites to ensure the proper and timely conduct of our clinical trials and while we have agreements governing their committed activities, we have limited influence over their actual performance. We depend on our CROs to support the conduct of our clinical trials in compliance with good clinical practice, or GCP, requirements. To the extent our CROs fail to help oversee the conduct the study in compliance with GCP standards or are delayed for a significant time in the execution of the trial, including achieving full enrollment, we may be affected by increased costs, program delays or both. In addition, clinical trials that are conducted in countries outside the United States may subject us to further delays and expenses as a result of increased shipment costs, additional regulatory requirements and the engagement of non- U. S. CROs, as well as expose us to risks associated with clinical investigators who are unknown to the FDA, and different standards of diagnosis, screening and medical care. Failure can occur at any stage of clinical testing. Our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and non- clinical testing in addition to those we have planned. Our failure to adequately demonstrate the safety and effectiveness of our systems or any product we may develop in the future would prevent receipt of regulatory approval, a granted de novo classification, or 510 (k) clearance and, ultimately, the commercialization of that product or indication for use. Even if our future products are approved, de novo classified, or cleared in the United States, commercialization of our products in foreign countries would require approval by regulatory authorities in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials. Any of these occurrences could have an adverse effect on our business, financial condition and results of operations. Interim, " topline, " and preliminary data from our clinical trials that we announce or publish from time to time may change as more data become available and are subject to confirmation, audit, and verification procedures that could result in material changes in the final data. From time to time, we may publicly disclose preliminary or topline data from our preclinical studies and clinical trials,

which is based on a preliminary analysis of then- available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations, and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data ~~are~~ **is** available. From time to time, we may also disclose interim data from our clinical trials. Interim or preliminary data from clinical trials are subject to the risk that one or more of the clinical outcomes may materially change as subject enrollment and treatment continues and more patient data become available or as subjects from our clinical trials continue other treatments for their disease. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock. Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the potential of the particular program, the likelihood of marketing approval, grant, clearance or commercialization of the particular product candidate, any marketed product, and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is derived from information that is typically extensive, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If the interim, topline, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition. If patients or physicians are not willing to change current practices to adopt our permanent birth control solution **or artificial insemination solution** ~~and women' s healthcare therapies~~ , our products may fail to gain increased market acceptance, and our business will be adversely affected. Our primary strategy to grow our revenue is to drive the adoption of our permanent birth control using the FemBloc system with an ultrasound confirmatory test, **our artificial insemination solution using the FemaSeed product and companion diagnostics,** and for physicians to employ our products to treat or diagnosis their patients with reproductive disorders or cancers. Physicians may choose not to adopt our ~~permanent birth control solution and~~ products for women' s healthcare for a number of reasons, including: • lack of availability of adequate third- party payor coverage or reimbursement; • lack of experience with our products and **more familiarity** with ~~permanent birth control and sonography~~ **other widely adopted products, procedures or treatments** as ~~treatment~~ alternatives; • our inability to convince key opinion leaders to provide recommendations regarding our **products** ~~permanent birth control solution~~ , or to convince physicians, patients and healthcare payors that our **products are** ~~permanent birth control solution is~~ an attractive alternative to **currently accepted alternatives** ~~surgical tubal ligation or other contraception options~~ ; • perceived inadequacy of evidence supporting clinical benefits, safety or cost- effectiveness of our **products** ~~permanent birth control solution over~~ existing alternatives; • liability risks generally associated with the use of new products and procedures; and • the training required to use new products. ~~We~~ **With respect to FemBloc, we intend to** focus our sales, marketing and training efforts primarily on obstetrical and gynecological physicians. However, physicians from other disciplines, including primary care physicians, as well as other medical professionals, such as nurse practitioners and physician assistants, are often the initial point of contact for patients with contraceptive needs. We believe that educating physicians in these disciplines and other medical professionals about the clinical merits, patient benefits and safety profile of our permanent birth control solution is an element of increasing the adoption of our FemBloc system. If additional physicians or other medical professionals do not appreciate and recommend our permanent birth control solution for any reason, including those listed above, our ability to execute our growth strategy will be impaired, and our business may be adversely affected. In addition, patients may not be able to adopt or may choose not to adopt our permanent birth control solution if, among other potential reasons, their anatomy would not allow for effective treatment with our FemBloc system, they are reluctant to receive a permanent solution to their contraceptive needs, they are worried about potential adverse effects of our permanent birth control solution, such as infection or discomfort, or they are unable to obtain adequate third- party coverage or reimbursement. **With respect** ~~If we fail~~ to ~~obtain a granted de novo classification from the FDA to market and sell the~~ FemaSeed ~~product~~ , ~~or if the review of the novo classification request is delayed,~~ we ~~will be unable to commercially distribute and market FemaSeed in the United States. The process of requesting de novo classification to market a medical device is expensive and time consuming. There can be no assurance that the de novo classification request will be granted. If we are not successful in obtaining timely grant of the FemaSeed product de novo classification request from the FDA, we may never be able to generate revenue. We are currently requesting de novo classification of the FemaSeed product for localized directional intrauterine insemination. The de novo process necessitates submitters to demonstrate that general controls, or general and special controls, are sufficient to provide reasonable assurance of safety and effectiveness and that the probable benefits of the device outweigh the probable risks. The de novo request is supported by extensive data, including, but not limited to, technical, preclinical, and often also clinical trial data. Even if our current clinical trial shows positive results, the FDA may not grant de novo classification or may require additional clinical trials. The FDA can delay, limit or deny a granted de novo classification for a device for many reasons, including: • we may not be able to demonstrate to the FDA' s satisfaction that general controls, or general and special controls, are sufficient to provide reasonable assurance of safety and effectiveness of our product for its intended~~ -- **intend** ~~use; • the FDA may disagree that the probable benefits of the device outweigh the probable risks; and • the FDA may disagree that the data from our manufacturing activities, preclinical studies and clinical trial are sufficient~~ to ~~support de novo classification. The process of obtaining de novo classification from the FDA could result in costs for us and consume management' s time and other resources. The FDA could ask us to supplement our submission, collect additional nonclinical~~

~~data, conduct additional clinical trials or engage in other time- consuming actions, or it could simply deny our request for the de novo classification. If we are unable to obtain and maintain the necessary regulatory authorizations, our financial condition may be adversely affected, and our ability to grow domestically and internationally would likely be limited. If patients or physicians are not willing to change current practices to adopt our artificial insemination solution, our system may fail to gain increased market acceptance, and our business will be adversely affected. Our primary strategy to grow our revenue is to drive the adoption of our artificial insemination solution using FemaSeed product for physicians to treat their patients with infertility. Physicians may choose not to adopt our artificial insemination solution and companion diagnostic device for women' s healthcare for a number of reasons, including: • lack of experience with our products and with intrauterine insemination and sonography as treatment alternatives; • our inability to convince key opinion leaders to provide recommendations regarding our artificial insemination solution, or to convince physicians and patients that our localized directional intrauterine insemination product is an attractive alternative to other intrauterine insemination options or other assisted reproductive options; • perceived inadequacy of evidence supporting clinical benefits, safety or cost effectiveness of our intrauterine artificial insemination product over existing alternatives; We~~ focus our sales, marketing and training efforts initially on reproductive endocrinologist physicians with possible expansion to gynecologists who are often the initial point of contact for patients with infertility needs. We believe that educating physicians in these disciplines and other medical professionals about the clinical merits and patient benefits of our artificial insemination solution is an element of increasing the adoption of our FemaSeed product. If additional physicians or other medical professionals do not appreciate and recommend our FemaSeed product for any reason, including those listed above, our ability to execute our growth strategy will be impaired, and our business may be adversely affected. If we are unable to achieve and maintain adequate levels of coverage or reimbursement for our **artificial insemination solution,** permanent birth control solution, or any other products we seek to commercialize, our commercial success may be severely hindered. The primary customers for our products are **reproductive endocrinologists for our infertility products and** obstetrics- gynecological physicians, related healthcare professionals, **and** women' s healthcare provider organizations ~~, and reproductive endocrinologists for our infertility products~~ . Our customers typically bill various third- party payors to cover all or a portion of the costs and fees associated with the procedures in which our products are used and bill patients for any deductibles or co- payments . Many third- party payors currently..... impair our ability to grow our business . Limited third- party payors provide infertility coverage with patient cash pay often required for treatment and services. **.** Many third- party payors currently cover contraceptive related procedures as part of the Patient Protection and Affordable Care Act,as amended by the Health Care and Education and Reconciliation Act,or,collectively,the ACA.If there are changes to the ACA related to contraceptive coverage,any decline in the amount payors will reimburse our customers could make it difficult for customers to elect choosing or to adopt our FemBloc system and could create additional pricing pressure for us.If we are forced to lower the price we charge for our product,our gross margins will decrease,which could have a material adverse effect on our business,financial condition and results of operations and impair our ability to grow our business ~~.~~ Third- party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, no uniform policy of coverage and reimbursement for procedures using our other products exists among third- party payors. Therefore, coverage and reimbursement for procedures using our other products can differ significantly from payor to payor. Payors continually review new and existing technologies for possible coverage and can, without notice, deny or reverse coverage for new or existing products and procedures. There can be no assurance that third- party payor policies will provide coverage for procedures in which our products are used. If we are not successful in reversing existing non- coverage policies, or if third- party payors that currently cover or reimburse our products and related procedures reverse or limit their coverage in the future, or if other third- party payors issue similar policies, this could have a material adverse effect on our business. Further, we believe that future coverage and reimbursement may be subject to increased restrictions, such as additional prior authorization requirements, both in the United States and in international markets. Third- party coverage and reimbursement for procedures using our products or any of our products in development for which we may receive regulatory approval may not be available or adequate in either the United States or international markets, which could have an adverse effect on our business, financial condition and results of operations and impair our ability to grow our business. Third- party payors and physicians who do not cover or use our **artificial insemination solution,** permanent birth control solution or other women' s healthcare devices may require additional clinical data prior to adopting or maintaining coverage of our **products** ~~FemBloc system~~ . Our success depends on physician and **where applicable** third- party payor acceptance of our **artificial insemination and** permanent birth control ~~solution~~ **solutions** as ~~an~~ effective treatment ~~option~~ **options** and our other healthcare devices for women. If physicians or payors do not find our body of published clinical evidence and data compelling or wish to wait for additional studies, they may choose not to use or provide coverage and reimbursement for our products. Currently, **patient cash pay is often required for infertility treatment and services, but** most large third- party payors cover permanent birth control as part of the ACA. ~~In addition, the long- term effects of use of our women' s healthcare products beyond five years are not yet known.~~ Certain physicians, hospitals and payors may prefer to see longer- term safety and efficacy data **for our permanent birth control solution** than we have produced. We cannot provide assurance that any data that we or others may generate in the future will be consistent with that observed in our existing clinical trials. The training required for physicians to use our **artificial insemination solution and** permanent birth control ~~solution and artificial insemination~~ solution could reduce the market acceptance of our products. As with any new method or technique, physicians must undergo a thorough training program before they perform the procedure. Even after successfully completing the training program, physicians could still experience difficulty in successfully providing the solutions and, as a result, limit use of the products significantly in their practice or cease utilizing it altogether. In addition, we may experience difficulty growing the number of physicians who complete our training program if patient demand is low, if the length of time necessary to train each physician is longer than expected, if the capacity of our sales representatives to train physicians is less than expected or if we are unable to sufficiently grow our sales

organization. All of these events would lead to fewer trained physicians to provide our solutions, which could negatively affect our business, financial condition and results of operations and impair our ability to grow our business. We currently compete and will in the future continue to compete against other companies, some of which have longer operating histories, more established products or greater resources than we do, which may prevent us from achieving increased market penetration and improved operating results. The biomedical industry is highly competitive, subject to change and significantly affected by new product introductions and other activities of industry participants. Our competitors have historically dedicated, and will continue to dedicate, significant resources to promoting their products or developing new products or methods to treat women' s reproductive issues and healthcare. We consider our primary potential competition to be other biomedical companies marketing women- specific medical products **. Having received FDA clearance for FemaSeed, we are the only localized directional intratubal insemination approach within the intrauterine insemination category approved for commercialization in North America, but compete with other fertility treatments such as traditional IUI and IVF. For our other FDA- cleared devices, we currently compete with other medical device providers in the United States and Canada** . Once we have received FDA approval, we will be the only non- surgical permanent birth control solution approved for commercialization ~~in the United States. Once we receive FDA de novo classification, we will be the only localized directional intrauterine insemination solution approved for commercialization in the United States. For our other FDA- cleared devices, we currently compete with other medical device providers in the United States~~ . We also believe other emerging businesses may be in the early stages of developing women- specific medical products ~~.~~ If one or more manufacturers successfully develops a product for providing localized directional ~~intratubal~~ **intrauterine** insemination that is more effective or otherwise more attractive than our artificial insemination solution,sales of our FemaSeed product could be significantly and adversely affected,which could have a material adverse effect on our business,financial condition and results of operations.In addition,if other companies are successful in developing products that are approved for a broader range of indications than our **intrauterine** artificial ~~intratubal~~ insemination system,we will be at a further competitive disadvantage,which could also affect our business,financial condition and results of operations **.** . If one or more manufacturers successfully develops a product for providing permanent birth control that is more effective, better tolerated or otherwise results in better compliance by patients, or otherwise more attractive than our permanent birth control solution, sales of our FemBloc system could be significantly and adversely affected, which could have a material adverse effect on our business, financial condition and results of operations. In addition, if other companies are successful in developing devices that are approved for a broader range of indications than our permanent birth control system, we will be at a further competitive disadvantage, which could also affect our business, financial condition and results of operations. If one or more manufacturers successfully develops..... financial condition and results of operations. Many of the companies against which we may compete may have competitive advantages with respect to primary competitive factors in the women' s healthcare market, including: • greater company, product and brand recognition; • superior product safety, reliability and durability; • better quality and larger volume of clinical data; • more effective marketing to and education of patients and physicians; • more sales force experience and greater market access; • better product support and service; • more advanced technological innovation, product enhancements and speed of innovation; • more effective pricing and revenue strategies; • lower procedure costs to patients; • more effective reimbursement teams and strategies; • dedicated practice development; and • more effective clinical training teams. We also compete with other biomedical companies to recruit and retain qualified sales, training and other personnel. In addition, though there are currently no pharmacologic therapies approved to provide permanent birth control, we may in the future face competition from pharmaceutical companies that develop such therapies. We also expect to experience increased competition in the future as other companies develop and commercialize competing women specific devices. Any of these companies may also have the competitive advantages described above. Our long- term growth depends on our ability to enhance our **artificial insemination solution,** permanent birth control solution ~~, artificial insemination solution,~~ and women- specific medical product solutions, expand our indications and develop and commercialize additional products. It is important to our business that we continue to enhance our **artificial insemination product,** permanent birth control system ~~, intrauterine artificial insemination product,~~ women- specific medical product solutions and develop and introduce new products. Developing products is expensive and time- consuming and could divert management' s attention away from our core business. The success of any new product offering or product enhancements will depend on several factors, including our ability to: • properly identify and anticipate physician and patient needs; • develop and introduce new products and product enhancements in a timely manner; • avoid infringing upon the intellectual property rights of third- parties; • demonstrate, if required, the safety and effectiveness of new products with data from preclinical studies and clinical trials; • obtain the necessary regulatory clearances, grants or approvals for expanded indications, new products or product modifications; • be fully FDA- compliant with marketing of new products or modified products; • provide adequate training to potential users of our products; • receive adequate coverage and reimbursement for procedures performed with our products; and • develop an effective and dedicated sales and marketing team. If we are not successful in expanding our indications and developing and commercializing new products and product enhancements, our ability to increase our revenue may be impaired, which could have a material adverse effect on our business, financial condition and results of operations. Our results of operations could be materially harmed if we are unable to accurately forecast customer demand for our **artificial insemination solution,** permanent birth control ~~solution, artificial insemination~~ solution, and women- specific medical products and manage our inventory. To ensure adequate inventory supply, we must forecast inventory needs and place orders with our suppliers based on our estimates of future demand for our products. Our ability to accurately forecast demand for our products could be negatively affected by many factors, including our failure to accurately manage our expansion strategy, product introductions by competitors, an increase or decrease in customer demand for our **artificial insemination product,** permanent birth control system, ~~artificial insemination product~~ and women- specific medical products or for products of our competitors, our failure to accurately forecast customer acceptance of new products, unanticipated changes in general market conditions or regulatory matters and weakening of economic conditions or

consumer confidence in future economic conditions. For example, tubal ligation procedures sustained an 18 % decline in December 2020 compared to December 2019, according to a study published in the publication Contraception in 2021. We have no assurance that demand for elective reproductive surgery will return to pre- pandemic levels in the future, or at all. Inventory levels in excess of customer demand may result in inventory 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 third- party suppliers may not be able to deliver components to meet our requirements, and this could result in damage to our reputation and customer relationships. In addition, if we experience a significant increase in demand, additional supplies of raw materials or additional manufacturing capacity may not be available when required on terms that are acceptable to us, or at all, or suppliers may not be able to allocate sufficient capacity in order to meet our increased requirements, which could have an adverse effect on our ability to meet customer demand for our products and our results of operations. We seek to maintain sufficient levels of inventory and components in order to protect ourselves from supply interruptions. As a result, we are subject to the risk that a portion of our inventory will become obsolete or expire, which could have a material adverse effect on our earnings and cash flows due to the resulting costs associated with the inventory impairment charges and costs required to replace such inventory. We manufacture and assemble components for our products and product candidates, and a loss or degradation in **the** performance of our manufacturing capabilities could have a material adverse effect on our business, financial condition and results of operations. We manufacture and assemble components used in our **artificial insemination product,** permanent birth control system, ~~artificial insemination product~~ and women- specific medical products. Our ability to maintain sufficient levels of inventory for our products could be negatively affected by many factors, including our failure to accurately manage our staffing requirements or a decrease in production capabilities. Conversely, if we overestimate customer demand for our **artificial insemination product,** permanent birth control system, ~~artificial insemination product~~ and women- specific medical products, our production staff may be in excess of that needed, and this could result in excess cost, which could have a material adverse effect on our business, financial condition and results of operations. We rely on a limited number of third- party suppliers for components for our products, as well as the sterilization of certain of our products, and a loss or degradation in performance of these suppliers could have a material adverse effect on our business, financial condition and results of operations. We rely on third- party suppliers for the raw materials and components used in our **artificial insemination product,** permanent birth control system, ~~artificial insemination product~~ and women- specific medical products. These suppliers may be unwilling or unable to supply the necessary materials and components reliably and at the levels we anticipate or that are required by the market. Our ability to supply our products commercially and to develop any future products depends, in part, on our ability to obtain these materials, components and products in accordance with regulatory requirements and in sufficient quantities for commercialization and clinical testing. While our suppliers have generally met our demand for their products and services on a timely basis in the past, we cannot guarantee that they will in the future be able to meet our demand for their products, either because of acts of nature, or our relative importance to them as a customer, and our suppliers may decide in the future to discontinue or reduce the level of business they conduct with us. If we are required to change suppliers due to any change in or termination of our relationships with these third parties, or if our suppliers are unable to obtain the materials they need to produce our components at consistent prices or at all, we may have to make modifications or changes to our products triggering the need for additional regulatory clearances or approvals, lose sales, experience manufacturing or other delays, incur increased costs or otherwise experience impairment to our customer relationships. We cannot guarantee that we will be able to establish alternative relationships on similar terms, without delay or at all. While we believe replacement suppliers exist for all materials, components and services necessary to manufacture our products, establishing additional or replacement suppliers for any of these materials, components or services, if required, could be time- consuming and expensive, may result in interruptions in our operations and product delivery, may affect the performance specifications of our products or could require that we modify its design. Even if we are able to find replacement suppliers, we will be required to verify that the new supplier maintains facilities, procedures and operations that comply with our quality expectations and applicable regulatory requirements. Furthermore, our suppliers could require us to use alternative materials or components. Any of these events could require that we obtain a new regulatory authority approval before we implement the change, which could result in further delay and which may not be obtained at all. While we seek to maintain sufficient levels of inventory as discussed above, those inventories may not fully protect us from supply interruptions. We have only limited supply arrangements in place with respect to certain components of our manufacturing process, and these arrangements do not extend to full commercial supply. We acquire certain key materials on a purchase order basis. As a result, we do not have long- term committed arrangements with respect **to** certain of the materials for our **products and** product candidates and other materials. If we obtain marketing approval, grant or clearance for our product candidates, we will need to establish an agreement for commercial manufacture of certain key materials with a third party. In addition, we are dependent on a sole supplier for certain components of our manufacturing process. Our current dependence on a single supplier for these components and the challenges we may face in obtaining adequate replacements involves several risks, including limited control over pricing, availability, quality and delivery schedules. Even if we are able to replace any raw materials or other materials with an alternative, such alternatives may cost more, result in lower yields or not be as suitable for our purposes. In addition, some of the materials that we use to manufacture our product candidates are complex materials, which may be more difficult to substitute. Therefore, any disruptions arising from our sole suppliers could result in delays and additional regulatory submissions. Our current and anticipated future dependence upon others for the manufacture of certain components of our product candidates or products may adversely affect our business, financial condition and results of operations. Moreover, we rely on third- party sterilizers to effectively sterilize our products and product candidates and failure of any third- party sterilizer could result in safety risks associated with our products and product candidates and could result in patient or study subject injuries which could expose our company to product liability claims and actions. Contract sterilizers are inspected by the FDA and may be inspected by foreign regulatory authorities.

Additionally, the closures and potential closures of facilities that use ethylene oxide to sterilize medical devices prior to their use may create delays or interruptions in the supply chain for our products and product candidates. Any compliance failures at any contract sterilizers we may contract with for sterilization of our products and product candidates also could create supply chain delays and interruptions and may require that we identify and contract with alternative contract sterilizers which we may not be able to do timely or on terms favorable to us. Any failures in the performance of our contract sterilizers may adversely affect our business, financial condition and results of operations. Performance issues, service interruptions or price increases by our shipping carriers could adversely affect our business and harm our reputation and ability to provide our services on a timely basis. Expedited, reliable shipping is essential to our operations. We rely heavily on providers of transport services for reliable and secure point- to- point transport of our products to our customers and for tracking of these shipments. Should a carrier encounter delivery performance issues such as loss, damage or destruction of any systems, it would be costly to replace such systems in a timely manner and such occurrences may damage our reputation and lead to decreased demand for our products and increased cost and expense to our business. In addition, any significant increase in shipping rates could adversely affect our operating margins and results of operations. Similarly, strikes, severe weather, natural disasters or other service interruptions affecting delivery services we use would adversely affect our ability to process orders for our products on a timely basis. Consolidation in the healthcare industry or group purchasing organizations could lead to demands for price concessions, which may affect our ability to sell our products at prices necessary to support our current business strategies. Healthcare costs have risen significantly over the past decade, which has resulted in or led to numerous cost reform initiatives by legislators, regulators and third- party payors. Cost reform has triggered a consolidation trend in the healthcare industry to aggregate purchasing power, which may create more requests for pricing concessions in the future. Additionally, group purchasing organizations, independent delivery networks and large single accounts may continue to use their market power to consolidate purchasing decisions for hospitals and physician practices. We expect that market demand, government regulation, third- party coverage and reimbursement policies and societal pressures will continue to change the healthcare industry worldwide, resulting in further business consolidations and alliances among our customers, which may exert further downward pressure on the prices of our products. We have limited experience marketing and selling our women- specific medical product solutions, and if we are unable to expand, manage and maintain our direct sales and marketing organization we may not be able to generate revenue growth. We have limited experience marketing and selling our women- specific medical products. We currently sell our **FemaSeed device,** FemVue device, FemCerv device, and FemCath device through a very limited direct effort, that targets obstetrician- gynecologist physicians, reproductive endocrinologist physicians, and physician practices in **North America** ~~the United States~~, including online training and new customer support, and also utilize various direct- to- patient marketing initiatives, including social media, a physician locator on a patient website, and online videos. As of December 31, ~~2022~~ **2023**, we have ~~five~~ **one** ~~employees~~ **employee exclusively** involved in our sales and marketing efforts. Our operating results are directly dependent upon the efforts of these employees. In order to generate future revenue growth, we ~~plan to~~ **are in the process of** ~~develop~~ **developing** geographic scope of a direct sales organization ~~once~~ **now that** the FemaSeed product **is available in the U. S. and Canadian market. This is expected to represent a significant expansion of our commercialization efforts, costs and attention. Our success depends largely on our ability to hire, train, retain and motivate skilled sales and marketing personnel with significant industry experience and technical knowledge of related products. Because the competition for their services is high, we cannot assure you we will be able to hire and retain additional personnel on favorable or commercially reasonable terms, if at all. Failure to hire or retain qualified sales and marketing personnel would prevent us from expanding our business and generating revenue. If we are unable to expand our sales and marketing capabilities, we may not be able to effectively commercialize our FemaSeed product and other women- specific medical products, which could have** ~~and~~ **an** ~~subsequently~~ **adverse effect on our business, financial condition and results of operations. In order to further expand revenue growth once the** FemBloc system ~~are~~ **is** available in the U. S. market **, we plan to enlarge the geographic scope of the direct sales organization**. Our future success will depend largely on our ability to hire, train, retain and motivate **additional** skilled sales and marketing personnel with significant industry experience and technical knowledge of related products. ~~Because the competition for their services is high, we cannot assure you we will be able to hire and retain additional personnel on favorable or commercially reasonable terms, if at all. Failure to hire or retain qualified sales and marketing personnel would prevent us from expanding our business and generating revenue.~~ If we are unable to expand our sales and marketing capabilities, we may not be able to effectively commercialize our ~~FemaSeed product,~~ FemBloc system ~~and other women- specific medical products~~, which could have an adverse effect on our business, financial condition and results of operations. To successfully market and sell our **artificial insemination product,** permanent birth control system, ~~artificial insemination product~~ and women specific medical product solutions in markets outside of the United States, we must address many international business risks with which we have limited experience. Our strategy is to increase our international presence in Europe, as well as, other international markets, such as Japan, which may further increase our revenue from markets outside the United States. International sales are subject to a number of risks, including: • difficulties in securing distribution partnerships and managing our international relationships; • increased competition as a result of more products and procedures receiving regulatory approval or otherwise free to market in international markets; • longer accounts receivable payment cycles and difficulties in collecting accounts receivable; • reduced or varied protection for intellectual property rights in some countries; • export restrictions, trade regulations, and foreign tax laws; • fluctuations in currency exchange rates; • foreign certification and regulatory clearance or approval requirements; • customs clearance and shipping delays; • political, social, and economic instability abroad, terrorist attacks, and security concerns in general; • preference for locally produced products; • potentially adverse tax consequences, including the complexities of foreign value- added tax systems; • the burdens of complying with a wide variety of foreign laws and different legal standards; and • increased financial accounting and reporting burdens and complexities. If one or more of these risks are realized, our business, financial

condition and results of operations could be adversely affected. We plan to rely on our own direct sales force for our women-specific medical products, which may result in higher fixed costs than our competitors and may slow our ability to reduce costs in the face of a sudden decline in demand for our products. We plan to rely on our own direct sales force in **North America** ~~the United States~~ and third- party distribution partners in Europe and other international countries, to market and sell our products. Some of our competitors rely predominantly on independent sales agents and third- party distributors. A direct sales force may subject us to higher fixed costs than those of companies that market competing products through independent third parties, due to the costs that we will bear associated with employee benefits, training and managing sales personnel. As a result, we could be at a competitive disadvantage. Additionally, these fixed costs may slow our ability to reduce costs in the face of a sudden decline in demand for our products, which could have a material adverse effect on our business, financial condition and results of operations. We face the risk of product liability claims that could be expensive, divert management' s attention and harm our reputation and business. We may not be able to maintain adequate product liability insurance. Our business exposes us to the risk of product liability claims that are inherent in the testing, manufacturing and marketing of medical products, including sterile medical products. This risk exists even if it is approved or cleared for commercial sale by the FDA and manufactured in facilities licensed and regulated by the FDA or an applicable foreign regulatory authority. Our FemBloc system and FemaSeed product are designed to affect, and any future products will be designed to affect, important bodily functions and processes, such as the female reproductive system. Any side effects, manufacturing defects, misuse or abuse associated with our FemBloc system, FemaSeed product and other women specific medical products, including sterilization failures, could result in patient injury or death. The medical device industry has historically been subject to extensive litigation over product liability claims, and we cannot offer any assurance that we will not face product liability suits. For example, Essure, a permanent birth control system previously marketed by Bayer, involved the implant of coils into a woman' s fallopian tubes by way of a hysteroscope, where they were to permanently remain. In 2016, the FDA ordered Bayer to conduct a post- market surveillance study and required a box warning to the product labeling, which included a warning of possible perforation of the uterus and / or fallopian tubes, identification of inserts in the abdominal or pelvic cavity, persistent pain, and suspected allergic or hypersensitivity reactions. In April 2018, **the** FDA restricted the sale and distribution of Essure. The product was removed by Bayer from all markets, including the U. S. effective December 2018. There can be no assurance that serious adverse safety concerns may not arise with the FemBloc system. We may be subject to product liability claims if our products cause, or merely appear to have caused, patient injury or death. In addition, an injury that is caused by the activities of our suppliers, such as those who provide us with components and raw materials, or any contract sterilizer, may be the basis for a claim against us. Product liability claims may be brought against us by patients, healthcare providers or others selling or otherwise coming into contact with our products, among others. If we cannot successfully defend ourselves against product liability claims, we will incur substantial liabilities and reputational harm. In addition, regardless of merit or eventual outcome, product liability claims may result in: • costs of litigation; • distraction of management **'** ~~'~~ **'** s attention from our primary business; • the inability to commercialize our current and future products; • decreased demand for our current and future products; • damage to our business reputation; • product recalls or withdrawals from the market; • withdrawal of clinical trial participants; • substantial monetary awards to patients or other claimants; or • loss of sales. While we may attempt to manage our product liability exposure by proactively recalling or withdrawing from the market any defective products, any recall or market withdrawal of our products may delay the supply of those products to our customers and may impact our reputation. We can provide no assurance that we will be successful in initiating appropriate market recall or market withdrawal efforts that may be required in the future or that these efforts will have the intended effect of preventing product malfunctions and the accompanying product liability that may result. Such recalls and withdrawals may also be used by our competitors to harm our reputation for safety or be perceived by patients as a safety risk when considering the use of our products, either of which could have a material adverse effect on our business, financial condition and results of operations. Although we have product liability and clinical trial liability insurance that we believe is appropriate, this insurance is subject to deductibles and coverage limitations. Our current product liability insurance may not continue to be available to us on acceptable terms, if at all, and, if available, coverage may not be adequate to protect us against any future product liability claims. If we are unable to obtain insurance at an acceptable cost or on acceptable terms or otherwise protect against potential product liability claims, we could be exposed to significant liabilities. A product liability claim, recall or other claim with respect to uninsured liabilities or for amounts in excess of insured liabilities could have a material adverse effect on our business, financial condition and results of operations. If the quality of our **artificial insemination product,** permanent birth control system, ~~artificial insemination product~~ and women- specific medical product solutions does not meet the expectations of physicians or patients, then our brand and reputation or our business could be adversely affected. In the course of conducting our business, we must adequately address quality issues that may arise with our **artificial insemination product,** permanent birth control system, ~~artificial insemination product~~ and women- specific medical product solutions, including defects in third- party components included in our products. Although we have established internal procedures designed to minimize risks that may arise from quality issues, there can be no assurance that we will be able to eliminate or mitigate occurrences of these issues and associated liabilities. In addition, even in the absence of quality issues, we may be subject to claims and liability if the performance of our products do not live up to the expectations of physicians or patients. If the quality of our products do not meet the expectations of physicians or patients, then our brand and reputation with those physicians or patients, or our business, financial condition and results of operations, could be adversely affected. If we choose to acquire new and complementary businesses, products or technologies, we may be unable to complete these acquisitions or to successfully integrate them in a cost- effective and non- disruptive manner. Our success depends, in part, on our ability to continually enhance and broaden our product offerings in response to changing customer demands, competitive pressures and advances in technologies. Accordingly, although we have no current commitments with respect to any acquisition or investment, we may in the future pursue the acquisition of, or joint ventures relating to, complementary businesses, products or technologies instead of

developing them ourselves. We do not know if we will be able to successfully complete any future acquisitions or joint ventures, or whether we will be able to successfully integrate any acquired business, product or technology or retain any key employees related thereto. Integrating any business, product or technology we acquire could be expensive and time- consuming, disrupt our ongoing business and distract our management. If we are unable to integrate any acquired businesses, products or technologies effectively, our business will be adversely affected. In addition, any amortization or charges resulting from the costs of acquisitions could increase our expenses. Risks Related to Managing Growth and Employee Matters We face risks related to health epidemics and outbreaks, including the COVID- 19 pandemic, which could significantly disrupt our clinical trials, and therefore our receipt of necessary regulatory approvals, clearances or grants could be delayed or prevented. We face risks related to health epidemics or outbreaks of communicable diseases. For example, in December 2019, a novel strain of coronavirus, SARS- CoV- 2, causing a disease referred to as COVID- 19, emerged in China. Since then, COVID- 19 ~~has~~ spread to multiple countries worldwide, including the United States and member states of the European Union. In March 2020, the World Health Organization declared the outbreak of COVID- 19 as a pandemic. The outbreak of such communicable diseases could result in a widespread health crisis that could adversely affect general commercial activity and the economies and financial markets of many countries, which in the case of COVID- 19 has occurred. The COVID- 19 pandemic ~~has~~ resulted in governments implementing numerous containment measures, such as travel bans and restrictions, particularly quarantines, shelter- in- place or total lock- down orders and business limitations and shutdowns. These containment measures are subject to change and the respective government authorities may tighten the restrictions at any time. We are following, and plan to continue to follow, recommendations from federal, state and local governments regarding workplace policies, practices and procedures. We are complying with all applicable guidelines for our clinical trials, including remote clinical monitoring. We ~~are continuing to monitor the potential impact of the pandemic, but we~~ cannot be certain what the overall impact will be on our business, financial condition, results of operations and prospects. In addition, the COVID- 19 pandemic **had** ~~is having~~ a severe effect on the clinical trials of many ~~device~~ **devices** and drug candidates. Some trials **were** ~~have been~~ merely delayed, while others **were** ~~have been~~ cancelled. The extent to which the COVID19 pandemic may impact our clinical trial operations will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration and geographic reach of ~~the~~ **an** outbreak, the severity of COVID- 19 **and future variants**, and the effectiveness of actions to contain and treat COVID- 19. To date, we ~~have~~ experienced delays in site initiation and subject enrollment in our clinical trials **. Possible** ~~and we may continue to experience some~~ delays **may** ~~in our clinical trial and delays in data collection and analysis. These delays so far~~ have ~~had~~ a severe impact, and ~~the continued spread of COVID- 19 globally and the continued identification of new variants of the SARS- CoV- 2 virus~~ could adversely impact our clinical trial operations ~~further~~, including our access to clinical trial sites and our ability to recruit and retain subjects and principal investigators and site staff who, as healthcare providers, may have heightened exposure ~~to COVID- 19~~ if an outbreak occurs in their geography. Disruptions on our ability to travel for trial support, monitor data from our clinical trials, or to conduct clinical trials, or the ability of subjects enrolled in our studies to travel, or the ability of staff at study sites to travel, as well as temporary closures or delays of our facilities or the facilities of our clinical trial partners and their contract manufacturers, would negatively impact our clinical trial activities. In addition, we rely on independent clinical investigators, CROs and other third- party service providers to assist us in managing, monitoring and otherwise carrying out our preclinical studies and clinical trials, including the collection of data from our clinical trials, and the ~~continued~~ **possible** spread of COVID- 19 or variants may affect their ability to be present, devote sufficient time and resources to our programs, or to travel to sites to perform work for us. Similarly, our preclinical trials could be delayed and / or disrupted by **a** ~~the COVID- 19~~ pandemic. As a result, the expected timeline for data readouts of our preclinical studies and clinical trials and certain regulatory filings may ~~continue to~~ be negatively impacted, which would adversely affect our ability to obtain regulatory approval for and to commercialize our product candidates, increase our operating expenses and have a material adverse effect on our business, financial condition, results of operations and prospects. Failure of a key information technology system, process or site could have an adverse effect on our business. We rely extensively on information technology systems to conduct our business. These systems affect, among other things, ordering and managing materials from suppliers, shipping products to customers, processing transactions, summarizing and reporting results of operations, complying with regulatory, legal or tax requirements, data security and other processes necessary to manage our business. If our systems are damaged or cease to function properly due to any number of causes, ranging from catastrophic events to power outages to security breaches, and our business continuity plans do not effectively compensate on a timely basis, we may experience interruptions in our operations, which could have an adverse effect on our business. Furthermore, any breach in our IT systems could lead to the unauthorized access, disclosure and use of non- public information, including information from our patient registry or other patient information, which is protected by HIPAA and other laws. Any such access, disclosure, or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, and damage to our reputation. In addition, we accept payments for some of our sales through credit and debit card transactions, which are handled through a third- party payment processor. As a result, we are subject to a number of risks related to credit and debit card payments. As a result of these transactions, we pay interchange and other fees, which may increase over time and could require us to either increase the prices we charge for our products or experience an increase in our costs and expenses. In addition, as part of the payment processing process, we transmit our customers **'** ~~'~~ credit and debit card information to our third- party payment processor. We may in the future become subject to lawsuits or other proceedings for purportedly fraudulent transactions arising out of the actual or alleged theft of our customers **'** ~~'~~ credit or debit card information if the security of our third- party credit card payment processor is breached. We and our third- party credit card payment processor are also subject to payment card association operating rules, certification requirements and rules governing electronic funds transfers, which could change or be reinterpreted to make it difficult or impossible for us to comply. If we or our third- party credit card payment processor fail to comply with these rules or requirements, we may be subject to fines and higher transaction fees and lose our

ability to accept credit and debit card payments from our customers, and there may be an adverse effect on our business. If our facilities are damaged or become inoperable, we will be unable to continue to research, develop, manufacture and supply our products and, as a result, there will be an adverse effect on our business until we are able to secure a new facility and rebuild our inventory. We do not have redundant facilities. We perform substantially all of our research, development, manufacturing and back - office activity and maintain all our finished goods inventory in a single location in Suwanee, Georgia. Our facility, equipment and inventory would be costly to replace and could require substantial lead time to repair or replace. The facility may be harmed or rendered inoperable by natural or man- made disasters, including, but not limited to, tornadoes, flooding, fire and power outages, which may render it difficult or impossible for us to perform our research, development and commercialization activities for some period of time. The inability to perform those activities, combined with the time it may take to rebuild our inventory of finished product, may result in the loss of customers or harm to our reputation. Although we possess insurance for damage to our property and the disruption of our business, this insurance may not be sufficient to cover all of our potential losses and this insurance may not continue to be available to us on acceptable terms, or at all. Our ability to maintain our competitive position depends on our ability to attract and retain senior management and other highly qualified personnel. Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and other personnel. We are highly dependent upon our management team, particularly our Chief Executive Officer and President and the rest of our senior management, and other key personnel. Although we have entered into employment letter agreements with all of our executive officers, each of them may terminate their employment with us at any time. The replacement of any of our key personnel likely would involve significant time and costs and may significantly delay or prevent the achievement of our business objectives and could therefore have an adverse effect on our business. In addition, we do carry " key person " insurance policy for our Chief Executive Officer and President that could offset potential loss of service under applicable circumstances. We will need to grow the size of our organization, and we may experience difficulties in managing this growth. As of December 31, ~~2022~~ **2023** , we had ~~34~~ **32** full- time employees, 2 part- time employees and ~~18~~ **21** consultants. As our development and commercialization plans and strategies develop, 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, including the clinical and FDA application preparation for our product candidates, 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 commercialize **our products and** any product candidates that are approved for marketing 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 its attention away from day- to- day activities in order to devote a substantial amount of time to managing these growth activities. We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services, including substantially all aspects of legal and compliance, regulatory marketing authorization, clinical trial management and manufacturing. There can be no assurance that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval of our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all. If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and **commercialize our products and** potentially commercialize our product candidates and, accordingly, may not achieve our research, development and commercialization goals. The increasing use of social media platforms presents new risks and challenges. Social media is increasingly being used to communicate about our clinical development programs and we intend to utilize appropriate social media in connection with our commercialization efforts **for our products and** following approval of our product candidates, if any. Social media practices in the biomedical industry continue to evolve and regulations and regulatory guidance relating to such use are evolving and not always clear. This evolution creates uncertainty and risk of noncompliance with regulations applicable to our business, resulting in potential regulatory actions against us, along with the potential for litigation related to off- label marketing or other prohibited activities and heightened scrutiny by the FDA, the SEC and other regulators. For example, patients may use social media channels to comment on their experience in an ongoing clinical trial or to report an alleged adverse event. If such disclosures occur, there is a risk that trial enrollment may be adversely impacted, that we may fail to monitor and comply with applicable adverse event reporting obligations or that we may not be able to defend our business or the public' s legitimate interests in the face of the political and market pressures generated by social media due to restrictions on what we may say about our product candidates. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us or the products we are marketing or developing on any social networking website. In addition, we may encounter attacks on social media regarding our company, management, product candidates or products. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face regulatory actions or incur other harm to our business. Risks Related to Government Regulation Our products and operations are subject to extensive government regulation and oversight both in the United States and abroad, and our failure to comply with applicable requirements could harm our business. We and our products are subject to extensive regulation in the United States and elsewhere, including by the FDA and its foreign counterparts. The FDA and foreign regulatory authorities regulate, among other things, with respect to medical devices: design, development and manufacturing; testing, labeling, clinical trials; product safety; establishment registration and device listing; marketing, sales

and distribution; pre- market clearance and approval; complaint handling; record keeping procedures; advertising and promotion; recalls and field safety corrective actions; post- market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, would be likely to cause or contribute to death or serious injury; post- market approval studies; and product import and export. The regulations to which we are subject are complex and have tended to become more stringent over time. Regulatory changes could result in restrictions on our ability to carry on or expand our operations, higher than anticipated costs or lower than anticipated sales. The FDA enforces these regulatory requirements through periodic unannounced inspections. We do not know whether **the** FDA will identify any areas of ~~non- compliance~~ **noncompliance** in any future FDA inspections or those conducted by foreign regulatory authorities. Failure to comply with applicable regulations could jeopardize our ability to sell our products and result in enforcement actions such as: warning letters; fines; injunctions; civil penalties; termination of distribution; recalls or seizures of products; delays in the introduction of products into the market; total or partial suspension of production; refusal to grant future approvals; withdrawals or suspensions of approvals, and in the most serious cases, criminal penalties. We may not receive the necessary approvals, granted de novo classifications, or clearances for our FemBloc system ~~, FemaSeed product~~ or future devices and expanded indications, and failure to timely obtain these marketing authorizations would adversely affect our ability to grow our business. Our strategy is dependent on FDA approval of our FemBloc system ~~and FDA grant of a de novo classification request for our FemaSeed product~~ . In the United States, before we can market a new medical device, or a new use of, certain new claims for, or significant modifications to an existing product, we must first receive either clearance under Section 510 (k) of the Federal Food, Drug, and Cosmetic Act, or the FDCA, de novo classification under Section 513 (f) (2) of the FDCA, or approval of 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 a proposed device is " substantially equivalent " to a legally- marketed " predicate " device, which includes a device that has been previously cleared through the 510 (k) process, a device that was legally marketed prior to May 28, 1976 (pre- amendments device), a device that was originally on the U. S. market pursuant to an approved PMA and later down-classified, a device that was de novo classified under section 513 (f) (2) of the FDCA, or a 510 (k)- exempt device. To be " substantially equivalent, " the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. Clinical data are sometimes required to support substantial equivalence demonstrations. The de novo classification process ~~, which is the anticipated premarket review pathway for our FemaSeed product,~~ provides a pathway to classify novel medical devices for which general controls alone, or general and special controls, provide reasonable assurance of safety and effectiveness for the device with the proposed intended use, but for which there is no legally marketed predicate device. A de novo classification is a risk- based classification process through which devices are classified into class I or class II. Devices classified in response to a de novo classification request may be marketed and used as predicates for future premarket notification 510 (k) submissions. In the process of obtaining PMA approval, which is required for our FemBloc system, 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 trial, 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. Modifications to products that are approved through a PMA application generally require FDA approval. Similarly, certain modifications made to products cleared through a 510 (k) or granted a de novo classification may require a new 510 (k) clearance, or could require a new de novo classification request or even a PMA. The PMA approval, de novo classification, and the 510 (k) clearance processes can be expensive, lengthy and uncertain. The FDA ~~'~~ **'** s 510 (k) clearance process usually takes from three to seven months, but can last longer, while the de novo classification process is usually longer and often requires a clinical trial. The process of obtaining a PMA is much more costly and uncertain than the de novo or 510 (k) clearance processes and generally takes one year, or even longer, from the time the application is filed with the FDA. In addition, a PMA generally requires the performance of one or more clinical trials. Despite the time, effort and cost, a device may not be approved, granted a de novo classification, or cleared by the FDA. Any delay or failure to obtain necessary regulatory authorizations could harm our business. Furthermore, even if we are granted 510 (k) clearances, de novo classifications, or approvals, they may include significant limitations on the indications for uses for the device, which may limit the market for the device. In the United States, we are currently seeking approval of our permanent birth control system through the PMA pathway ~~and grant of a de novo classification for our artificial insemination product~~ . Even if the PMA is approved, any future modification to our permanent birth control system may require us to submit a new PMA or PMA supplement and obtain FDA approval prior to implementing the change, although some modifications can be reported in an annual report or through a 30- day Notice. The FDA may not agree with our decisions regarding whether a new PMA or PMA supplement is necessary. If the FDA requires us to go through a lengthier, more rigorous process for future products or modifications to existing products than we had expected, product introductions or modifications could be delayed or canceled, which could adversely affect our ability to grow our business. The FDA or foreign regulatory bodies can delay, limit or deny a marketing authorization of 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 or, for a 510 (k) device, that they are substantially equivalent to the predicate; • the disagreement of the FDA or the applicable foreign regulatory body with the design or implementation of our clinical trials or the interpretation of data from preclinical studies or clinical trials; • serious and unexpected adverse device effects experienced by participants in our clinical trials; • the data from our preclinical studies and clinical trials may be insufficient to support approval, de novo classification or clearance where required; • our inability to demonstrate that the clinical and other benefits of the device outweigh the risks; • the manufacturing process or facilities we use may not meet applicable requirements; and • the potential for approval policies or regulations of the FDA or applicable foreign regulatory bodies to change significantly in a manner rendering our clinical data or regulatory filings

insufficient to support a marketing authorization. In addition, the FDA may change its policies, adopt additional regulations or revise existing regulations, or take other actions, which may prevent or delay approval, de novo classification or clearance of our future products under development or impact our ability to modify our currently cleared products on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain new approvals, granted de novo classifications, or 510 (k) clearances, or increase the costs of compliance or restrict our ability to maintain our current 510 (k) clearances. For example, as part of the FDA Reauthorization Act, or FDARA, in 2017, Congress reauthorized the Medical Device User Fee Amendments with various FDA performance goal commitments and enacted several regulatory improvements related to devices and miscellaneous reforms, which are further intended to clarify and improve medical device regulation both pre- and post- clearance and approval. Some of these proposals and reforms could impose additional regulatory requirements upon us that could delay our ability to obtain new approvals, granted de novo classifications, or 510 (k) clearances, or increase the costs of compliance. The Medical Devices Regulation (Regulation (EU) 2017 / 745) became fully applicable on 26 May 2021, repealing and replacing the pre- existing EU Medical Devices Directive (Council Directive 93 / 42 / EEC). In order to sell our products in member countries of the EEA our products must comply with the essential requirements of the Medical Devices Regulation, subject to certain transitional provisions that allow continued compliance of certain products to the Medical Devices Directive until May 2024 at the latest. Compliance with these requirements is a prerequisite to be able to affix the Conformité Européene, or CE, mark to our products, without which they cannot be sold or marketed in the EEA. To demonstrate compliance with the essential requirements we must perform a conformity assessment procedure, which varies according to the type of medical device and its classification. Except for low- risk medical devices (Class I non- sterile, non-measuring devices), where the manufacturer can issue an EC Declaration of Conformity based on a self- assessment of the conformity of its products with the essential requirements of the EU Medical Devices Regulation, a conformity assessment procedure requires the intervention of an organization accredited by a member state of the EEA to conduct conformity assessments, or a notified body. Depending on the relevant conformity assessment procedure, the notified body would typically audit and examine the technical file and the quality system for the manufacture, design and final inspection of our devices. The notified body issues a certificate of conformity following successful completion of a conformity assessment procedure conducted in relation to the medical device and its manufacturer and their conformity with the essential requirements. This certificate entitles the manufacturer to affix the CE mark to its medical devices after having prepared and signed a related EC Declaration of Conformity. Since 26 May 2021, all manufacturers of medical devices sold in the EEA have to be compliant with the rules set out in the Medical Devices Regulation. The Medical Devices Regulation has the same basic requirements as the repealed EU Medical Devices Directive, but is generally more stringent, especially in terms of risk classes and the oversight provided by notified bodies. There is also more emphasis on vigilance and post- market surveillance. As a general rule, demonstration of conformity of medical devices and their manufacturers with the essential requirements must be based, among other things, on the evaluation of clinical data supporting the safety and performance of the products during normal conditions of use. Specifically, a manufacturer must demonstrate that the device achieves its intended performance during normal conditions of use, that the known and foreseeable risks, and any adverse events, are minimized and acceptable when weighed against the benefits of its intended performance, and that any claims made about the performance and safety of the device are supported by suitable evidence. If we fail to remain in compliance with applicable European laws, we would be unable to continue to affix the CE mark to our products, which would prevent us from selling them within the EEA. All medical devices must be registered with the MHRA before being placed on the Great Britain, or GB, market. FemVue is a Class I device and ~~we expect~~ FemaSeed **is** ~~to be~~ a Class IIb device and **we expect** FemBloc to be a Class III device. European CE marks will continue to be recognized in GB until June 30, 2023, following which a UKCA mark will be required for a medical device to be marketed in GB. The EU regulatory framework on medical devices will, however, continue to apply in Northern Ireland under the Northern Irish Protocol and medical devices in Northern Ireland may either carry a European CE mark or a CE UKNI mark (although devices bearing the CE UKNI marking can only be placed on the market in Northern Ireland and will not be accepted on the EU market). As a general rule, demonstration of conformity of medical devices and their manufacturers with the essential requirements must be based, among other things, on the evaluation of clinical data supporting the safety and performance of the products during normal conditions of use. Specifically, a manufacturer must demonstrate that the device achieves its intended performance during normal conditions of use, that the known and foreseeable risks, and any adverse events, are minimized and acceptable when weighed against the benefits of its intended performance, and that any claims made about the performance and safety of the device are supported by suitable evidence. If we fail to remain in compliance with applicable European laws and directives, we would be unable to continue to affix the CE mark to our products, which would prevent us from selling them within the EEA. Modifications to our products may require us to obtain new PMA approvals or approvals of a PMA supplement, and if we market modified products without obtaining necessary approvals, we may be required to cease marketing or recall the modified products until required approvals are obtained. Certain modifications to a PMA- approved device may require approval of a new PMA or a PMA supplement, while other modifications can be reported in an annual report or through a 30- day Notice. The FDA may not agree with our decisions regarding whether a new PMA or PMA supplement is necessary. We may make modifications to our approved devices in the future that we believe do not require approval of a new PMA or PMA supplement. If the FDA disagrees with our determination and requires us to submit a new PMA or PMA supplement for modifications to our previously approved products, we may be required to cease marketing or to recall the modified product until we obtain approval, and we may be subject to significant regulatory fines or penalties. For de novo classified or 510 (k) cleared devices we will need to submit a new 510 (k) premarket notification for any change or modification in the device that could significantly affect the safety or effectiveness of the device, or for a major change or modification in the intended use of the device. **The** FDA may not agree with our determination whether a new 510 (k) is required for a modification, in which case we may be required to cease marketing or recall the modified product until we receive 510 (k) clearance. In addition, the FDA

may not approve, de novo classify, or clear our products for the indications that are necessary or desirable for successful commercialization or could require clinical trials to support any modifications. Any delay or failure in obtaining required authorizations would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth. Failure to comply with post- marketing regulatory requirements could subject us to enforcement actions, including substantial penalties, and might require us to recall or withdraw a product from the market. After approval for our permanent birth control system, we will be subject to ongoing and pervasive regulatory requirements governing, among other things, the manufacture, marketing, labeling, packaging, advertising, medical device reporting, sale, promotion, registration, storage, distribution and listing of devices. For example, we must submit periodic reports to the FDA as a condition of PMA approval. These reports include safety and effectiveness information about the device after its approval. Failure to submit such reports, or failure to submit the reports in a timely manner, could result in enforcement action by the FDA. Following its review of the periodic reports, the FDA might ask for additional information or initiate further investigation. In addition, the PMA approval for our FemBloc system may be subject to several conditions of approval, including a post- market extended follow- up of the pre- market study cohort. Any failure to comply with the conditions of approval could result in the withdrawal of PMA approval and the inability to continue to market the device. Adverse outcomes in these studies could also be grounds for withdrawal of approval of the PMA. The regulations to which we are subject are complex and have become more stringent over time. Regulatory changes could result in restrictions on our ability to continue or expand our operations, higher than anticipated costs, or lower than anticipated sales. Even after we have obtained the proper regulatory authorization to market a device, we have ongoing responsibilities under FDA regulations and applicable foreign laws and regulations. The FDA, state and foreign regulatory authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA, state or foreign regulatory authorities, which may include any of the following sanctions: • untitled letters or warning letters; • fines, injunctions, consent decrees and civil penalties; • recalls, termination of distribution, administrative detention, or seizure of our products; • customer notifications or repair, replacement or refunds; • operating restrictions or partial suspension or total shutdown of production; • delays in or refusal to grant our requests for future PMA approvals or foreign regulatory approvals of new products, new intended uses, or modifications to existing products; • withdrawals or suspensions of our current PMA or foreign regulatory approvals, resulting in prohibitions on sales of our products; • FDA refusal to issue certificates to foreign governments needed to export products for sale in other countries; and • criminal prosecution. Any of these sanctions could result in higher than anticipated costs or lower than anticipated sales and have a material adverse effect on our reputation, business, financial condition and results of operations. Our products must be manufactured in accordance with federal and state regulations, and we or any of our suppliers could be forced to recall our products or terminate production if we fail to comply with these regulations. The methods used in, and the facilities used for, the manufacture of our products must comply with the FDA ' ' s Quality System Regulation, or QSR, which is a complex regulatory scheme that covers good manufacturing practices for the procedures and documentation of the design, testing, production, process controls, quality assurance, labeling, packaging, handling, storage, distribution, installation, and servicing of medical devices. Furthermore, we are required to verify that our suppliers and service providers maintain facilities, procedures and operations that comply with our quality standards and applicable regulatory requirements. The FDA enforces the QSR through periodic announced or unannounced inspections of medical device manufacturing facilities, which may include the facilities of subcontractors. Our products are also subject to similar state regulations, including state wholesale distribution requirements, and various laws and regulations of foreign countries governing manufacturing. We may not take the necessary steps to comply with applicable regulations, which could cause delays in the delivery of our products. In addition, failure to comply with applicable FDA requirements or later discovery of previously unknown problems with our products or manufacturing processes could result in, among other things: • warning letters or untitled letters; • fines, injunctions or civil penalties; • suspension or withdrawal of approvals; • seizures or recalls of our products; • total or partial suspension of production or distribution; • administrative or judicially imposed sanctions; • the FDA ' ' s refusal to grant pending or future approvals for our products; • clinical holds; refusal to permit the import or export of our products; and • criminal prosecution of us or our employees. Any of these actions could significantly and negatively affect supply of our products. If any of these events occurs, our reputation could be harmed, we could be exposed to product liability claims and we could lose customers and experience reduced sales and increased costs. If treatment guidelines for permanent birth control or other women healthcare treatments change or the standard of care evolves, we may need to redesign and seek new marketing authorization from the FDA for one or more of our products. If treatment guidelines for permanent birth control or other women healthcare treatments changes or the standard of care for any of these conditions evolve, we may need to redesign the applicable product and seek new clearances, grants or approvals from the FDA. If treatment guidelines change so that different treatments become desirable, the clinical utility of one or more of our products could be diminished and our business could be adversely affected. The misuse or off- label use of our products may harm our reputation in the marketplace, result in injuries that lead to product liability suits or result in costly investigations, fines or sanctions by regulatory bodies if we are deemed to have engaged in the promotion of these uses, any of which could be costly to our business. Although our products are marketed for the specific treatments for which the devices were designed and our personnel are trained not to promote our products for uses outside of the FDA- approved or cleared indications for use, known as " off- label uses ", we cannot, however, prevent a physician from using our products, when in the physician ' ' s independent professional medical judgment, he or she deems it appropriate. There may be increased risk of injury to patients if physicians attempt to use our products off- label. Furthermore, the use of our products for indications other than those approved, granted or cleared by the FDA or authorized by any foreign regulatory body may not effectively treat such conditions, which could harm our reputation in the marketplace among physicians and patients. If the FDA or any foreign regulatory body determines that our promotional materials or training constitute promotion of an off- label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance or imposition of warning letter

or an untitled letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action under other regulatory authority, such as false claims laws, if they consider our business activities to constitute promotion of an off- label use, which could result in significant penalties, including, but not limited to, criminal, civil and administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs and the curtailment of our operations. In addition, physicians may misuse our products or use improper techniques if they are not adequately trained, potentially leading to injury and an increased risk of product liability. If our products are misused or used with improper technique, we may become subject to costly litigation by our customers or their patients. Similarly, in an effort to decrease costs, physicians may also reuse our products despite it being intended for a single use or may purchase reprocessed products from third- party reprocessors in lieu of purchasing a new product from us, which could result in product failure and liability. As described above, product liability claims could divert management ~~'~~**'** s attention from our core business, be expensive to defend and result in sizeable damage awards against us that may not be covered by insurance. Our products may cause or contribute to adverse medical events or be subject to failures or malfunctions that we are required to report to the FDA, and if we fail to do so, we would be subject to sanctions that could harm our reputation, business, financial condition and results of operations. The discovery of serious safety issues with our products, or a recall of our products either voluntarily or at the direction of the FDA or another governmental authority, could have a negative impact on us. We are subject to the FDA ~~'~~**'** s medical device reporting regulations and similar foreign regulations, which require us to report to the FDA when we receive or become aware of information that reasonably suggests that one or more of our products may have caused or contributed to a death or serious injury or malfunctioned in a way that, if the malfunction were to recur, would be likely to cause or contribute to a death or serious injury. The timing of our obligation to report is triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events of which we become aware within the prescribed timeframe. We may also fail to recognize that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of the product. If we fail to comply with our reporting obligations, the FDA could take action, including warning letters, untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, seizure of our products or delay in clearance or approval of future products. The FDA and foreign regulatory bodies have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture of a product or in the event that a product poses an unacceptable risk to health. The FDA ~~'~~**'** s authority to require a recall must be based on a finding that there is reasonable probability that the device could cause serious, adverse health consequences or death. We may also choose to voluntarily recall a product if any material deficiency is found. A government- mandated or voluntary recall by us could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing defects, labeling or design deficiencies, packaging defects or other deficiencies or failures to comply with applicable regulations. Product defects or other errors may occur in the future. Depending on the corrective action we take to redress a product ~~'~~**'** s deficiencies or defects, the FDA may require, or we may decide, that we will need to obtain new clearances, grants or approvals for the device before we may market or distribute the corrected device. Seeking such clearances, grants or approvals may delay our ability to replace the recalled devices in a timely manner. Moreover, if we do not adequately address problems associated with our devices, we may face additional regulatory enforcement action, including FDA warning letters, product seizure, injunctions, administrative penalties or civil or criminal fines. Certain voluntary field actions are required to be reported to **the** FDA and other regulatory authorities. Companies are required to maintain certain records of recalls and corrections, even if they are not reportable to the FDA. We may initiate voluntary withdrawals or corrections for our products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, it could require us to report those actions as recalls and we may be subject to enforcement action. A future recall announcement could harm our reputation with customers, potentially lead to product liability claims against us and negatively affect our sales. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business and may harm our reputation and financial results. If we do not obtain and maintain international regulatory registrations or approvals for our products, we will be unable to market and sell our products outside of **North America** ~~the United States~~. Sales of our products outside of **North America** ~~the United States~~ are subject to foreign regulatory requirements that vary widely from country to country. In addition, the FDA regulates exports of medical devices from the United States. While the regulations of some countries may not impose barriers to marketing and selling our products or only require notification, others require that we obtain the approval of a specified regulatory body. Complying with foreign regulatory requirements, including obtaining registrations or approvals, can be expensive and time- consuming, and we may not receive regulatory approvals in each country in which we plan to market our products or we may be unable to do so on a timely basis. The time required to obtain registrations or marketing authorizations, if required by other countries, may be longer than that required for FDA clearance, grant or approval, and requirements for such registrations and marketing authorizations may significantly differ from FDA requirements. If we modify our products, we may need to apply for additional regulatory approvals before we are permitted to sell the modified product. In addition, we may not continue to meet the quality and safety standards required to maintain the authorizations that we have received. If we are unable to maintain our authorizations in a particular country, we will no longer be able to sell the applicable product in that country. Regulatory clearance, grant or approval or clearance by the FDA does not ensure registration or marketing authorization by regulatory authorities in other countries, and registration, clearance or approval by one or more foreign regulatory authorities does not ensure registration or marketing authorization by regulatory authorities in other foreign countries or by the FDA. However, a failure or delay in obtaining registration or marketing authorization in one country may have a negative effect on the regulatory process in others. Legislative or regulatory reforms in the United States or the European Union may make it more difficult and costly for us to obtain regulatory clearances or approvals for our products or to manufacture, market or distribute our products after clearance or

approval is obtained. From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulation of medical devices. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new statutes, regulations or revisions or reinterpretations of existing regulations, requirements, and regulatory processes may impose additional costs or lengthen review times of any future products or make it more difficult to obtain approval for, manufacture, market or distribute our products. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could, among other things, require: additional testing prior to obtaining clearance, grant or approval; changes to manufacturing methods; recall, replacement or discontinuance of our products; or additional record keeping. On April 5, 2017, the European Parliament passed the Medical Devices Regulation (Regulation 2017 / 745), which repeals and replaces the EU Medical Devices Directive and the EU Active Implantable Medical Devices Directive (Directive 90 / 385 / EEC) with effect from May 26, 2021. Unlike directives, which must be implemented into the national laws of the EEA member states, the Medical Devices Regulation is directly applicable, i. e., without the need for adoption of EEA member state laws implementing them, in all EEA member states and is intended to eliminate current differences in the regulation of medical devices among EEA member States. Once applicable, the Medical Devices Regulation will among other things: • strengthen the rules on placing devices on the market and reinforce surveillance once they are available; • establish explicit provisions on manufacturers ~~'~~ **'** responsibilities for the follow- up of the quality, performance and safety of devices placed on the market; • improve the traceability of medical devices throughout the supply chain to the end- user or patient through a unique identification number; • set up a central database to provide patients, healthcare professionals and the public with comprehensive information on products available in the EU; • strengthen rules for the assessment of certain high- risk devices, such as implants, which may have to undergo an additional check by experts before they are placed on the market. Under transitional provisions, medical devices with notified body certificates issued under the Medical Devices Directive prior to May 26, 2021 may continue to be placed on the market for the remaining validity of the certificate, until May 27, 2024 at the latest. After the expiry of any applicable transitional period, only devices that have been CE marked under the Medical Device Regulation may be placed on the market in the EEA. The new requirements introduced by the Medical Devices Regulation may make it harder for us to CE mark our products and may have an effect on the way we conduct our business in the EEA. We are subject to certain federal, state and foreign fraud and abuse laws, health information privacy and security laws and transparency laws, which, if violated, could subject us to substantial penalties. Additionally, any challenge to or investigation into our practices under these laws could cause adverse publicity and be costly to respond to, and thus could harm our business. There are numerous U. S. federal and state, as well as foreign, laws pertaining to healthcare fraud and abuse, including anti- kickback, false claims and physician transparency laws. Our business practices and relationships with providers are subject to scrutiny under these laws. We may also be subject to privacy and security regulation related to patient, customer, employee and other third- party information by both the federal government and the states and foreign jurisdictions in which we conduct our business. The healthcare laws and regulations that may affect our ability to operate include, but are not limited to: • the federal Anti- Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce either the referral of an individual or furnishing or arranging for a good or service, for which payment may be made, in whole or in part, under federal healthcare programs, such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation. The U. S. government has interpreted this law broadly to apply to the marketing and sales activities of manufacturers. Moreover, the government may assert that a claim including items or services resulting from a violation of the federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. Violations of the federal Anti- Kickback Statute may result in civil monetary penalties. Civil penalties for such conduct can further be assessed under the federal False Claims Act. Violations can also result in criminal penalties. Similarly, violations can result in exclusion from participation in government healthcare programs, including Medicare and Medicaid. On November 20, 2020, the Department of Health and Human Services' Office of the Inspector General, or OIG, finalized further modifications to the federal Anti- Kickback Statute. Under the final rules, the OIG added safe harbor protections under the Anti- Kickback Statute for certain coordinated care and value- based arrangements among clinicians, providers, and others. These ~~rule~~ **rules** (with exceptions) became effective January 19, 2021. We continue to evaluate what effect, if any, these rules will have on our business; • the federal civil and criminal false claims laws and civil monetary penalties laws, including the federal civil False Claims Act, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other federal healthcare programs that are false or fraudulent. These laws can apply to manufacturers who provide information on coverage, coding, and reimbursement of their products to persons who bill third- party payers. Private individuals can bring False Claims Act " qui tam " actions, on behalf of the government and such individuals, commonly known as " whistleblowers, " may share in amounts paid by the entity to the government in fines or settlement. When an entity is determined to have violated the federal civil False Claims Act, the government may impose civil fines and penalties, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs; • the federal Civil Monetary Penalties Law, which prohibits, among other things, offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary ~~'~~ **'** s decision to order or receive items or services reimbursable by the government from a particular provider or supplier; • the Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal statutes that prohibit, among other things, executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters. Similar to the federal Anti- Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation; • the federal Physician Sunshine Act under the ACA, which require certain applicable manufacturers of drugs, devices, biologics and medical supplies

for which payment is available under Medicare, Medicaid or the Children ’ s Health Insurance Program, or CHIP, to report annually to the DHHS Centers for Medicare and Medicaid Services, or CMS, information related to payments and other transfers of value to physicians, which is defined broadly to include other healthcare providers and teaching hospitals, and applicable manufacturers and group purchasing organizations, to report annually ownership and investment interests held by physicians and their immediate family members. Applicable manufacturers are required to submit annual reports to CMS. Failure to submit required information may result in civil monetary penalties for all payments, transfers of value or ownership or investment interests that are not timely, accurately, and completely reported in an annual submission, and may result in liability under other federal laws or regulations. We have not, to date, submitted reports under the Physician Sunshine Act under the ACA; • HIPAA, as amended by the HITECH Act, and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans and healthcare clearinghouses as well as their business associates that perform services for them that involve individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization, including mandatory contractual terms as well as directly applicable privacy and security standards and requirements. Failure to comply with the HIPAA privacy and security standards can result in civil monetary penalties, and, in certain circumstances, criminal penalties. State attorneys general can also bring a civil action to enjoin a HIPAA violation or to obtain statutory damages on behalf of residents of his or her state; • analogous state and foreign law equivalents of each of the above federal laws, such as anti- kickback and false claims laws which may apply to items or services reimbursed by any third- party payor, including commercial insurers or patients; state laws that require device companies to comply with the industry ’ s voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm customers, foreign and state laws, including the EU General Data Protection Regulation, governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts; federal government price reporting laws, which may require calculations and reporting of complex pricing metrics in an accurate and timely manner to government programs; and state laws related to insurance fraud in the case of claims involving private insurers; and • California recently enacted the California Consumer Privacy Act (CCPA) which creates new individual privacy rights for California consumers (as defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA will require covered companies to provide certain disclosures to consumers about its data collection, use and sharing practices, and to provide affected California residents with ways to opt- out of certain sales or transfers of personal information. The CCPA went into effect on January 1, 2020, and the California State Attorney General submitted final regulations for review on June 2, 2020, which were finalized and are now effective. The California State Attorney General has commenced enforcement actions against violators as of July 1, 2020. Further, a new California privacy law, the California Privacy Rights Act (CPRA) was passed by California voters on November 3, 2020. The CPRA created obligations relating to consumer data beginning on January 1, 2022 and enforcement of the law begins on July 1, 2023. We will continue to monitor developments related to the CPRA and anticipate additional costs and expenses associated with CPRA compliance. Laws similar to the CCPA and CPRA have been enacted in Virginia (the Virginia Consumer Data Protection Act, or VCDPA, which went into effect on January 1, 2023), Colorado (the Colorado Privacy Act, or CPA, which goes into effect on July 1, 2023), Utah (the Utah Consumer Privacy Act, or UCPA, which goes into effect on December 31, 2023) and Connecticut (the Connecticut Data Privacy Act, or CDPA, which goes into effect on July 1, 2023). The California Age- Appropriate Design Code Act (CAADCA), which expands the CPRA for businesses with websites that are likely to be accessed by children, was signed into law on September 15, 2022 and goes into effect on July 1, 2024. While the CCPA and CPRA contain an exception for certain activities involving PHI under HIPAA, we cannot yet determine the impact the CCPA, CPRA or other such future laws, regulations and standards may have on our business. These laws and regulations, among other things, constrain our business, marketing and other promotional activities by limiting the kinds of financial arrangements, including sales programs, we may have with hospitals, physicians or other potential purchasers of our products. Due to the breadth of these laws, the narrowness of statutory exceptions and regulatory safe harbors available, and the range of interpretations to which they are subject, it is possible that some of our current or future practices might be challenged under one or more of these laws. To enforce compliance with the healthcare regulatory laws, certain enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Responding to investigations can be time- and resource- consuming and can divert management ’ s attention from the business. Additionally, as a result of these investigations, healthcare providers and entities may have to agree to additional compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business. Even an unsuccessful challenge or investigation into our practices could cause adverse publicity and be costly to respond to. If our operations are found to be in violation of any of the healthcare laws or regulations described above or any other healthcare regulations that apply to us, we may be subject to penalties, including administrative, civil and criminal penalties, damages, fines, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, imprisonment, contractual damages, reputational harm, disgorgement and the curtailment or restructuring of our operations. Inadequate funding for the FDA, the SEC and other government agencies, including from government shut downs, or other disruptions to these agencies’ operations, could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively

impact our business. The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and / or approved by necessary government agencies, which would adversely affect our business. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and / or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years the U. S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations. We may be subject to, or may in the future become subject to, U. S., state, and foreign laws and regulations imposing obligations on how we collect, store and process personal information. Our actual or perceived failure to comply with such obligations could harm our business. Ensuring compliance with such laws could also impair our efforts to maintain and expand our customer base, and thereby decrease our revenue. In the conduct of our business, we may at times process personal data, including health- related personal data. The U. S. federal government and various states have adopted or proposed laws, regulations, guidelines and rules for the collection, distribution, use and storage of personal information of individuals. We may also be subject to U. S. federal rules, regulations and guidance concerning data security for medical devices, including guidance from the FDA. State privacy and security laws vary from state to state and, in some cases, can impose more restrictive requirements than U. S. federal law. Where state laws are more protective, we must comply with the stricter provisions. In addition to fines and penalties that may be imposed for failure to comply with state law, some states also provide for private rights of action to individuals for misuse of personal information. The EU also has laws and regulations dealing with the collection, use and processing of personal data obtained from individuals in the EU, which are often more restrictive than those in the United States and which restrict transfers of personal data to the United States unless certain requirements are met. These obligations may be interpreted and applied in a manner that is inconsistent from one jurisdiction to another and may conflict with other requirements or our practices. In addition, these rules are constantly under scrutiny. For example, following a decision of the Court of Justice of the European Union in October 2015, transferring personal data to U. S. companies that had certified as members of the U. S. Safe Harbor Scheme was declared invalid. In July 2016 the European Commission adopted the U. S.- EU Privacy Shield Framework which replaces the Safe Harbor Scheme. However, this Framework is under review and there is currently litigation challenging other EU mechanisms for adequate data transfers (i. e., the standard contractual clauses). It is uncertain whether the Privacy Shield Framework and / or the standard contractual clauses will be similarly invalidated by the European courts. We rely on a mixture of mechanisms to transfer personal data from our EU business to the U. S., and could be impacted by changes in law as a result of a future review of these transfer mechanisms by European regulators under the EU General Data Protection Regulation (GDPR) as well as current challenges to these mechanisms in the European courts. Any actual or perceived failure by us or the third parties with whom we work to comply with privacy or security laws, policies, legal obligations or industry standards, or any security incident that results in the unauthorized release or transfer of personally identifiable information, may result in governmental enforcement actions and investigations including by European Data Protection Authorities and U. S. federal and state regulatory authorities, fines and penalties, litigation and / or adverse publicity, including by consumer advocacy groups, and could cause our customers, their patients and other healthcare professionals to lose trust in us, which could harm our reputation and have a material adverse effect on our business, financial condition and results of operations. The laws in the EU are under reform and from May 25, 2018 onwards, we will be subject to the requirements of the GDPR because we are processing personal data in the EU and / or offering goods to, or monitor the behavior of, individuals in the EU. The GDPR implements more stringent administrative requirements for controllers and processors of personal data, including, for example, shortened timelines for data breach notifications, limitations on retention of information, increased requirements pertaining to health data and pseudonymized (i. e., key- coded) data, additional obligations when we contract with service providers, more robust rights for individuals over their personal data. The GDPR provides that EU member states may make their own further laws and regulations limiting the processing of genetic, biometric or health data, which could limit our ability to use and share personal data or could cause our costs to increase and harm our business and financial condition. If we do not comply with our obligations under the GDPR, we could be exposed to significant fines of up to € 20, 000, 000 or up to 4 % of the total worldwide annual turnover of the preceding financial year, whichever is higher. Healthcare policy changes, including recently enacted legislation reforming the U. S. healthcare system, could harm our business, financial condition and results of operations. In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. In March 2010, the ACA was enacted in the United States, which made a number of substantial changes in the way healthcare is financed by both governmental and private insurers. Among other ways in which it may affect our business, the ACA: • imposed an annual excise tax of 2. 3 % on any entity that manufactures or imports medical devices offered for sale in the United States, with limited exceptions (described in more detail below), although the effective rate paid may be lower. Through a series of legislative amendments, the tax was suspended for 2016 through 2019. Absent further legislative action, the device excise tax was to be reinstated on medical device sales starting January 1, 2020. The Further Consolidated Appropriations Act, 2020 H. R. 1865 (Pub. L. 116- 94), signed into law on December 20, 2019, has repealed the medical device excise tax previously imposed by Internal Revenue Code section 4191. Prior to the repeal, the tax was on a 4- year moratorium. As a result of the repeal and

the prior moratorium, sales of taxable medical devices after December 31, 2015, are not subject to the tax. It is impossible to determine whether similar taxes could be instated in the future; • established a new Patient- Centered Outcomes Research Institute to oversee and identify priorities in comparative clinical efficacy research in an effort to coordinate and develop such research; • implemented payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models; and • expanded the eligibility criteria for Medicaid programs. We do not yet know the full impact that the ACA will have on our business. The taxes imposed by the ACA and the expansion in the government ' ' s role in the U. S. healthcare industry may result in decreased profits to us, lower reimbursement by payors for our permanent birth control system and women- specific medical devices, and / or reduced medical procedure volumes, all of which may have a material adverse effect on our business, financial condition and results of operations. Some of the provisions of the ACA have yet to be fully implemented, while certain provisions have been subject to judicial and Congressional challenges. Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017, or Tax Act, includes a provision that decreased the tax- based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year, commonly referred to as the " individual mandate, " to $ 0, effective January 1, 2019. On December 14, 2018, a federal district court in Texas ruled the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the ACA are invalid as well. On December 18, 2019, the Fifth Circuit U. S. Court of Appeals held that the individual mandate is unconstitutional, and remanded the case to the lower court to reconsider its earlier invalidation of the full ACA. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case and held oral arguments on November 10, 2020. Although the Biden Administration has reconsidered the position of the government on the constitutionality of the individual mandate and the severability of the provision from the remainder of the ACA and has officially notified the United States Supreme Court in this regard, pending a decision, the ACA remains in effect, but it is unclear at this time what effect these developments will have on the status of the ACA. Further, on January 20, 2017, former President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. On October 13, 2017, former President Trump signed an Executive Order terminating the cost- sharing subsidies that reimburse insurers under the ACA. The Trump administration concluded that cost- sharing reduction, (CSR) payments to insurance companies required under the ACA have not received necessary appropriations from Congress and announced that it will discontinue these payments immediately until those appropriations are made. Several state Attorneys General filed suit to stop the administration from terminating the subsidies, but their request for a restraining order was denied by a federal judge in California on October 25, 2017. On August 14, 2020, the U. S. Court of Appeals for the Federal Circuit ruled in two separate cases that the federal government is liable for the full amount of unpaid CSRs for the years preceding and including 2017. For CSR claims made by health insurance companies for years 2018 and later, further litigation will be required to determine the amounts due, if any. Further, on June 14, 2018, the U. S. Court of Appeals for the Federal Circuit ruled that the federal government was not required to pay more than $ 12 billion in ACA risk corridor payments to third- party payors who argued the payments were owed to them. On April 27, 2020, the United States Supreme Court reversed the U. S. Court of Appeals for the Federal Circuit ' ' s decision and remanded the case to the U. S. Court of Federal Claims, concluding the government has an obligation to pay these risk corridor payments under the relevant formula. It is unclear what impact these rulings will have on our business. In addition, CMS published a final rule that would give states greater flexibility as of 2020 in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces. In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, reduced Medicare payments to providers by 2 % per fiscal year, effective on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030 unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) enacted on April 16, 2015, repealed the formula by which Medicare made annual payment adjustments to physicians and replaced the former formula with fixed annual updates and a new system of incentive payments scheduled to begin in 2019 that are based on various performance measures and ~~physicians~~ **physician ' ' s** participation in alternative payment models such as accountable care organizations. It is unclear what effect new quality and payment programs, such as MACRA, may have on our business, financial condition, results of operations or cash flows. We expect additional state and federal healthcare policies and reform measures to be adopted in the future, any of which could limit reimbursement for healthcare products and services or otherwise result in reduced demand for our FemBloc system or additional pricing pressure and have a material adverse effect on our industry generally and on our customers. Any changes of, or uncertainty with respect to, future coverage or reimbursement rates could affect demand for our FemBloc system, which in turn could impact our ability to successfully commercialize our FemBloc system and could have a material adverse effect on our business, financial condition and results of operations. Our business involves the use of hazardous materials, and we must comply with environmental laws and regulations, which may be expensive and restrict how we do business. Our manufacturer activities involve the controlled storage, use and disposal of hazardous materials and are subject to federal, state, local and foreign laws and regulations governing the use, generation, manufacture, storage, handling and

disposal of these hazardous materials. We currently carry no insurance specifically covering environmental claims relating to the use of hazardous materials. Although we believe the safety procedures for handling and disposing of these materials and waste products comply with the standards prescribed by these laws and regulations, we cannot eliminate the risk of accidental injury or contamination from the use, storage, handling or disposal of hazardous materials. In the event of an accident, state or federal or other applicable authorities may curtail our use of these materials and interrupt our business operations which could adversely affect our business. We are subject to anti- bribery, anti- corruption, and anti- money laundering laws, including the U. S. Foreign Corrupt Practices Act, as well as export control laws, customs laws, sanctions laws and other laws governing our operations. If we fail to comply with these laws, we could be subject to civil or criminal penalties, other remedial measures and legal expenses, which could adversely affect our business, results of operations and financial condition. As we grow our international presence and global operations, we will be increasingly exposed to trade and economic sanctions and other restrictions imposed by the United States, the European Union and other governments and organizations. The U. S. Departments of Justice, Commerce, State and Treasury and other federal agencies and authorities have a broad range of civil and criminal penalties they may seek to impose against corporations and individuals for violations of economic sanctions laws, export control laws, the U. S. Foreign Corrupt Practices Act, (FCPA) and other federal statutes and regulations, including those established by the Office of Foreign Assets Control (OFAC). In addition, the U. K. Bribery Act of 2010, or the Bribery Act, prohibits both domestic and international bribery, as well as bribery across both private and public sectors. An organization that " fails to prevent bribery " by anyone associated with the organization can be charged under the Bribery Act unless the organization can establish the defense of having implemented " adequate procedures " to prevent bribery. Under these laws and regulations, as well as other anti- corruption laws, anti- money laundering laws, export control laws, customs laws, sanctions laws and other laws governing our operations, various government agencies may require export licenses, may seek to impose modifications to business practices, including cessation of business activities in sanctioned countries or with sanctioned persons or entities and modifications to compliance programs, which may increase compliance costs, and may subject us to fines, penalties and other sanctions. A violation of these laws or regulations would negatively affect our business, financial condition and results of operations. We have implemented policies and procedures that are designed to ensure compliance by us and our directors, officers, employees, representatives, consultants and agents with the FCPA, OFAC restrictions, the Bribery Act and other export control, anti- corruption, anti- money- laundering and anti- terrorism laws and regulations. We cannot assure you, however, that our policies and procedures are sufficient or that directors, officers, employees, representatives, consultants and agents have not engaged and will not engage in conduct for which we may be held responsible, nor can we assure you that our business partners have not engaged and will not engage in conduct that could materially affect their ability to perform their contractual obligations to us or even result in our being held liable for such conduct. Violations of the FCPA, OFAC restrictions, the Bribery Act or other export control, anti- corruption, anti- money laundering and anti- terrorism laws or regulations may result in severe criminal or civil sanctions, and we may be subject to other liabilities, which could have a material adverse effect on our business, financial condition and results of operations. We bear the risk of warranty claims on our products. We bear the risk of warranty claims on our products. We may not be successful in claiming recovery under any warranty or indemnity provided to us by our suppliers or vendors in the event of a successful warranty claim against us by a customer or that any recovery from such vendor or supplier would be adequate. In addition, warranty claims brought by our customers related to third- party components may arise after our ability to bring corresponding warranty claims against such suppliers expires, which could result in costs to us. Risks Related to Intellectual Property Matters If we are unable to adequately protect our intellectual property rights, or if we are accused of infringing on the intellectual property rights of others, our competitive position could be harmed or we could be required to incur significant expenses to enforce or defend our rights. Our commercial success will depend in part on our success in obtaining and maintaining issued patents, trademarks and other intellectual property rights in the United States and elsewhere and protecting our proprietary technology. If we do not adequately protect our intellectual property and proprietary technology, competitors may be able to use our technologies or the goodwill we have acquired in the marketplace and erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability. We own numerous issued patents and pending patent applications that relate to our **intrauterine artificial insemination product,** permanent birth control system ~~, intrauterine artificial insemination product,~~ and women- specific medical product solutions. As of December 31, ~~2022~~ **2023** , we owned ~~40~~ **48** issued U. S. patents and ~~122~~ **132** issued foreign patents, ~~13~~ **14** pending U. S. patent applications and ~~17~~ **25** pending foreign patent applications. These issued patents, and any patents granted from such applications, are expected to expire between ~~2023~~ **2024** and 2046, without taking potential patent term extensions or adjustments into account. We cannot provide any assurances that any of our patents have, or that any of our pending patent applications that mature into issued patents will include, claims with a scope sufficient to protect our **intrauterine artificial insemination product,** permanent birth control system, ~~intrauterine artificial insemination product~~ and women- specific medical product solutions, and any additional features we develop for our products. Other parties may have developed technologies that may be related or competitive to our **intrauterine artificial insemination product,** permanent birth control system, ~~intrauterine artificial insemination product~~ and women- specific medical product solutions, may have filed or may file patent applications and may have received or may receive patents that overlap or conflict with our patent applications, either by claiming the same methods or devices or by claiming subject matter that could dominate our patent position. The patent positions of medical device companies, including our patent position, may involve complex legal and factual questions, and, therefore, the scope, validity and enforceability of any patent claims that we may obtain cannot be predicted with certainty. Patents, if issued, may be challenged, deemed unenforceable, invalidated or circumvented. Proceedings challenging our patents could result in either loss of the patent or denial of the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. In addition, such proceedings may be costly. Thus, any patents that we may own may not provide any protection against competitors. Furthermore, an adverse decision in an interference proceeding can result in a third party

receiving the patent right sought by us, which in turn could affect our ability to commercialize our products. Though an issued patent is presumed valid and enforceable, its issuance is not conclusive as to its validity or its enforceability and it may not provide us with adequate proprietary protection or competitive advantages against competitors with similar products. Competitors could purchase our **intrauterine artificial insemination product,** permanent birth control system ~~, intrauterine artificial insemination product~~ , and women- specific medical product solutions and attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around our patents, or develop and obtain patent protection for more effective technologies, designs or methods. We may be unable to prevent the unauthorized disclosure or use of our technical knowledge or trade secrets by consultants, suppliers, vendors, former employees and current employees. The laws of some foreign countries do not protect our proprietary rights to the same extent as the laws of the United States, and we may encounter significant problems in protecting our proprietary rights in these countries. Our ability to enforce our patent rights depends on our ability to detect infringement. It may be difficult to detect infringers who do not advertise the components that are used in their products. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor ~~'~~ **'** s or potential competitor ~~'~~ **'** s product. 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, proceedings to enforce or defend our patents could put our patents at risk of being invalidated, held unenforceable or interpreted narrowly. Such proceedings could also provoke third parties to assert claims against us, including that some or all of the claims in one or more of our patents are invalid or otherwise unenforceable. If any of our patents covering our FemBloc system or FemaSeed product are invalidated or found unenforceable, or if a court found that valid, enforceable patents held by third parties covered one or more of our products, our competitive position could be harmed or we could be required to incur significant expenses to enforce or defend our rights. The degree of future protection for our proprietary rights is uncertain, and we cannot ensure that: • any of our patents, or any of our pending patent applications, if issued, will include claims having a scope sufficient to protect our FemBloc system and FemaSeed product; • any of our pending patent applications will issue as patents; • we will be able to successfully commercialize our products on a substantial scale, if approved, before our relevant patents we may have expire; • we were the first to make the inventions covered by each of our patents and pending patent applications; • we were the first to file patent applications for these inventions; • others will not develop similar or alternative technologies that do not infringe our patents; any of our patents will be found to ultimately be valid and enforceable; • any patents issued to us will provide a basis for an exclusive market for our commercially viable products, will provide us with any competitive advantages or will not be challenged by third parties; • we will develop additional proprietary technologies or products that are separately patentable; or • our commercial activities or products will not infringe upon the patents of others. We rely, in part, upon unpatented trade secrets, unpatented know- how and continuing technological innovation to develop and maintain our competitive position, which we seek to protect, in part, by confidentiality agreements with our employees and consultants. We also have agreements with our employees and consultants that obligate them to assign their inventions to us and have non- compete agreements with some, but not all, of our consultants. It is possible that technology relevant to our business will be independently developed by a person that is not a party to such an agreement. Furthermore, if the employees and consultants who are parties to these agreements breach or violate the terms of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets through such breaches or violations. Further, our trade secrets could otherwise become known or be independently discovered by our competitors. Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for ~~non- compliance~~ **noncompliance** with these requirements. Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and applications are required to be paid to the United States Patent and Trademark Office, or USPTO, and various governmental patent agencies outside of the United States in several stages over the lifetimes of the patents and applications. The USPTO and various non- U. S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process and after a patent has issued. There are situations in which ~~non- compliance~~ **noncompliance** can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Under the terms of some of our licenses, we do not have the ability to maintain or prosecute patents in the portfolio and must therefore rely on third parties to comply with these requirements. Litigation or other proceedings or third- party claims of intellectual property infringement could require us to spend significant time and money and could prevent us from developing or selling our products or affect our stock price. Our commercial success will depend in part on not infringing the patents or violating the other proprietary rights of others. Significant litigation regarding patent rights occurs in our industry. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use and sell our products. We do not always conduct independent reviews of patents issued to third parties. In addition, patent applications in the United States and elsewhere can be pending for many years before issuance, or unintentionally abandoned patents or applications can be revived, so there may be applications of others now pending or recently revived patents of which we are unaware. These applications may later result in issued patents, or the revival of previously abandoned patents, that will prevent, limit or otherwise interfere with our ability to make, use or sell our products. Third parties may, in the future, assert claims that we are employing their proprietary technology without authorization, including claims from competitors or from non- practicing entities that have no relevant product revenue and against whom our own patent portfolio may have no deterrent effect. As we continue to commercialize our products in their current or updated forms, launch new products and enter new markets, we expect competitors may claim that one or more of our products infringe their intellectual property rights as part of business strategies designed to impede our successful commercialization and entry into new markets. The large number of patents, the rapid rate of

new patent applications and issuances, the complexities of the technology involved, and the uncertainty of litigation may increase the risk of business resources and management ' ' s attention being diverted to patent litigation. We have, and we may in the future, receive letters or other threats or claims from third parties inviting us to take licenses under, or alleging that we infringe, their patents. Moreover, we may become party to future adversarial proceedings regarding our patent portfolio or the patents of third parties. Such proceedings could include supplemental examination or contested post- grant proceedings such as review, reexamination, inter parties review, interference or derivation proceedings before the U. S. Patent and Trademark Office and challenges in U. S. District Court. Patents may be subjected to opposition, post- grant review or comparable proceedings lodged in various foreign, both national and regional, patent offices. The legal threshold for initiating litigation or contested proceedings may be low, so that even lawsuits or proceedings with a low probability of success might be initiated. Litigation and contested proceedings can also be expensive and time- consuming, and our adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we can. We may also occasionally use these proceedings to challenge the patent rights of others. We cannot be certain that any particular challenge will be successful in limiting or eliminating the challenged patent rights of the third party. Any lawsuits resulting from such allegations could subject us to significant liability for damages and invalidate our proprietary rights. Any potential intellectual property litigation also could force us to do one or more of the following: • stop making, selling or using products or technologies that allegedly infringe the asserted intellectual property; • lose the opportunity to license our technology to others or to collect royalty payments based upon successful protection and assertion of our intellectual property rights against others; incur significant legal expenses; • pay substantial damages or royalties to the party whose intellectual property rights we may be found to be infringing; • pay the attorney ' ' s fees and costs of litigation to the party whose intellectual property rights we may be found to be infringing; • redesign those products that contain the allegedly infringing intellectual property, which could be costly, disruptive and infeasible; and • attempt to obtain a license to the relevant intellectual property from third parties, which may not be available on reasonable terms or at all, or from third parties who may attempt to license rights that they do not have. Any litigation or claim against us, even those without merit, may cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our core business and harm our reputation. If we are found to infringe the intellectual property rights of third parties, we could be required to pay substantial damages (which may be increased up to three times of awarded damages) and / or substantial royalties and could be prevented from selling our products unless we obtain a license or are able to redesign our products to avoid infringement. Any such license may not be available on reasonable terms, if at all, and there can be no assurance that we would be able to redesign our products in a way that would not infringe the intellectual property rights of others. We could encounter delays in product introductions while we attempt to develop alternative methods or products. If we fail to obtain any required licenses or make any necessary changes to our products or technologies, we may have to withdraw existing products from the market or may be unable to commercialize one or more of our products. In addition, we generally indemnify our customers with respect to infringement by our products of the proprietary rights of third parties. Third parties may assert infringement claims against our customers. These claims may require us to initiate or defend protracted and costly litigation on behalf of our customers, regardless of the merits of these claims. If any of these claims succeed or settle, we may be forced to pay damages or settlement payments on behalf of our customers or may be required to obtain licenses for the products they use. If we cannot obtain all necessary licenses on commercially reasonable terms, our customers may be forced to stop using our products. Third parties may assert ownership or commercial rights to inventions we develop. Third parties may in the future make claims challenging the inventorship or ownership of our intellectual property. We may face claims by third parties that our agreements with employees, contractors or consultants obligating them to assign intellectual property to us are ineffective or in conflict with prior or competing contractual obligations of assignment, which could result in ownership disputes regarding intellectual property we have developed or will develop and interfere with our ability to capture the commercial value of such intellectual property. Litigation may be necessary to resolve an ownership dispute, and if we are not successful, we may be precluded from using certain intellectual property or may lose our exclusive rights in that intellectual property. Either outcome could harm our business and competitive position. If we are unable to protect the confidentiality of our trade secrets, our business and competitive position could be harmed. In addition to patent protection, we also rely upon copyright and trade secret protection, as well as non- disclosure agreements and invention assignment agreements with our employees, consultants and third parties, to protect our confidential and proprietary information. In addition to contractual measures, we try to protect the confidential nature of our proprietary information using commonly accepted physical and technological security measures. Such measures may not, for example, in the case of misappropriation of a trade secret by an employee or third party with authorized access, provide adequate protection for our proprietary information. Our security measures may not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our products that we consider proprietary. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time- consuming, and the outcome is unpredictable. Even though we use commonly accepted security measures, 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, trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, our business and competitive position could be harmed. We may be unable to enforce our intellectual property rights throughout the world. The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. This could make it difficult for us to stop infringement of our foreign patents, if obtained, or the misappropriation of our other intellectual property

rights. For example, some foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, some countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. 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. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. In addition, changes in the law and legal decisions by courts in the United States and foreign countries may affect our ability to obtain adequate protection for our technology and the enforcement of our intellectual property. Third parties may assert that our employees or consultants have wrongfully used or disclosed confidential information or misappropriated trade secrets. We employ individuals who previously worked with other companies, including our competitors or potential competitors. Although we try to ensure that our employees 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 our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property or personal data, including trade secrets or other proprietary information, of a former employer or other third party. Litigation may be necessary to defend against these claims. If we fail in defending any such claims or settling those claims, in addition to paying monetary damages or a settlement payment, we may lose valuable intellectual property rights or personnel. 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. Recent changes in U. S. patent laws could diminish the value of patents in general and may limit our ability to obtain, defend and / or enforce our patents. Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. The Leahy- Smith America Invents Act, or the Leahy- Smith Act, includes a number of significant changes to U. S. patent law. These include provisions that affect the way patent applications are prosecuted and also affect patent litigation. The U. S. Patent and Trademark Office recently developed new regulations and procedures to govern administration of the Leahy- Smith Act, and many of the substantive changes to patent law associated with the Leahy- Smith Act, and in particular, the first to file provisions, which became effective on March 16, 2013. The first to file provisions limit the rights of an inventor to patent an invention if not the first to file an application for patenting that invention, even if such invention was the first invention. Accordingly, it is not clear what, if any, impact the Leahy- Smith Act will have on the operation of our business. However, the Leahy- Smith Act and its implementation could increase the uncertainties and costs surrounding the enforcement and defense of our issued patents. For example, the Leahy- Smith Act provides that an administrative tribunal known as the Patent Trial and Appeals Board, or PTAB, provides a venue for challenging the validity of patents at a cost that is much lower than district court litigation and on timelines that are much faster. Although it is not clear what, if any, long- term impact the PTAB proceedings will have on the operation of our business, the initial results of patent challenge proceedings before the PTAB since its inception in 2013 have resulted in the invalidation of many U. S. patent claims. The availability of the PTAB as a lower- cost, faster and potentially more potent tribunal for challenging patents could increase the likelihood that our own patents will be challenged, thereby increasing the uncertainties and costs of maintaining and enforcing them. Patent terms may be inadequate to protect our competitive position on our products for an adequate amount of time. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire shortly after such candidates are commercialized. We expect to seek extensions of patent terms in the United States and, if available, in other countries where we are prosecuting patents. In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 permits a patent term extension of up to five years beyond the normal expiration of the patent, which is limited to the approved indication (or any additional indications approved during the period of extension). However, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If our trademarks and trade names are denied by regulatory authorities or are not adequately protected, we may not be able to build name recognition in our markets of interest and our business may be adversely affected. We rely on our trademarks and trade names to distinguish our products from the products of our competitors and have registered or applied to register many of these trademarks. We cannot assure you that our trademark applications will be approved in a timely manner or at all. During the trademark registration process, we may receive office actions from the USPTO objecting to the registration of our trademark. Although we would be given an opportunity to respond to those objections, we may be unable to overcome them. Our registered or unregistered trademarks or trade names may be denied by other regulatory authorities or challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may be unable to use these trademarks and trade names or protect our rights to these trademarks and trade names, which we need to build name recognition by potential partners or customers in our markets of interest. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. If other entities use trademarks similar to ours in different jurisdictions, or have senior rights to ours, it could interfere with our use of our current trademarks throughout the world. If we are required to use an alternative trademark, any goodwill and recognition that we have built for these trademarks would be lost. If any party infringes **on** any of the trademarks on which we rely, enforcing those trademarks may be difficult, costly, time- consuming and ultimately unsuccessful. Risks Related to Our Common Stock We are a " smaller reporting company " and an " emerging growth company " and the reduced disclosure requirements applicable to " smaller reporting companies " may make our common stock less attractive to investors. We are an " emerging growth company, " as defined in the JOBS Act. We will remain an emerging growth company until the earlier of (i) the last day of the fiscal year (a) following the fifth anniversary of the completion of our IPO, (b) in which we have total annual gross revenue of at least $ 1.

07 billion or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non- affiliates exceeded $ 700. 0 million as of our most recently completed second fiscal quarter and (ii) the date on which we have issued more than $ 1. 0 billion in non- convertible debt during the prior three- year period. An emerging growth company may take advantage of specified reduced reporting requirements and other burdens that are otherwise applicable generally to public companies. These provisions include: • being permitted to present only two years of audited financial statements and only two years of related management' s discussion and analysis of financial condition and results of operations; • not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act; • an exemption from compliance with any new requirements adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotations; • reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements; and • exemptions from the requirement to hold a nonbinding advisory vote on executive compensation and to obtain stockholder approval of any golden parachute payments not previously approved. We have elected to take advantage of certain of the reduced disclosure obligations in and may elect to take advantage of other reduced reporting requirements in the future. As a result, the information that we provide to our investors may be different from the information you might receive from other public reporting companies that are not emerging growth companies in which you hold equity interests. The JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have elected not to take advantage of such extended transition period, which means that we will adopt a new standard when it is issued or revised. We are also a " smaller reporting company, " meaning that the market value of our shares held by non- affiliates is less than $ 700. 0 million and our annual revenue was less than $ 100. 0 million during the most recently completed fiscal year, or if the market value of our shares held by non- affiliates is less than $ 250. 0 million. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company, we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10- K and have reduced disclosure obligations regarding executive compensation, and, similar to emerging growth companies, if we are a smaller reporting company with less than $ 100 million in annual revenue, we would not be required to obtain an attestation report . Anti- takeover provisions in our charter documents 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. Provisions in the amended and restated certificate of incorporation and our amended and restated bylaws may delay or prevent an acquisition of us or a change in our management. In addition, 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. Because our board of directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt by our stockholders to replace current members of our management team. These provisions include: • a prohibition on actions by our stockholders by written consent; • advance notice requirements for election to our board of directors and for proposing matters that can be acted upon at stockholder meetings; • a requirement that directors may only be removed " for cause "; • a requirement that only the board of directors may change the number of directors and fill vacancies on the board; • division of our board of directors into three classes, serving staggered terms of three years each; and • the authority of the board of directors to issue preferred stock with such terms as the board of directors may determine. Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, as amended, 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. These provisions would apply even if the proposed merger or acquisition could be considered beneficial by some ~~stockholders. Our directors, officers and principal stockholders have significant voting power and may take actions that may not be in the best interests of our other stockholders. Our officers, directors and principal stockholders collectively control approximately 18. 7 of our outstanding common stock. As a result, these stockholders, if they act together, will be able to control the management and affairs of us and most matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. The interests of these stockholders may not be the same as or may even conflict with your interests. For example, these stockholders could attempt to delay or prevent a change in control, even if such change in control would benefit our other stockholders, which could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of us or our assets and might affect the prevailing market price of our common stock due to investors' perceptions that conflicts of interest may exist or arise. As a result, this concentration of ownership may not be in the best interests of our other~~ stockholders. We incur significant costs as a result of being a public company, which may adversely affect our business, financial condition and results of operations. We incur costs associated with corporate governance requirements that will are applicable to us as a public company, including rules and regulations of the SEC, under the Sarbanes- Oxley Act, the Dodd- Frank Wall Street Reform and Consumer Protection Act of 2010, and the Exchange Act, as well as the rules of Nasdaq. These rules and regulations have significantly increased our accounting, legal and financial compliance costs and have made some activities more time- consuming. These rules and regulations have made it more expensive for us to maintain directors' and officers' liability insurance. As a result, it may be more difficult for us to attract and retain qualified persons to serve on our board of directors or as executive officers. Accordingly, the increases in costs incurred as a result of being a publicly traded company may adversely affect our business, financial condition and results of operations. We are obligated to develop and maintain proper and effective internal controls over financial reporting and any failure to maintain the adequacy of these internal controls may adversely affect investor confidence in our Company and, as a result, the value of our common stock. To comply with the requirements of being a public

company, we have undertaken various actions, including implementing new internal controls and procedures and hiring new accounting or internal audit staff. The Sarbanes- Oxley Act requires that we maintain effective disclosure controls and procedures and internal control over financial reporting. We are continuing to develop and refine our disclosure controls and other procedures that are designed to ensure that information required to be disclosed by us in the reports that we file with the SEC is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, and that information required to be disclosed in reports under the Exchange Act is accumulated and communicated to our principal executive and financial officers. Our current controls and any new controls that we develop may become inadequate and weaknesses in our internal control over financial reporting may be discovered in the future. Any failure to develop or maintain effective controls when we become subject to this requirement could negatively affect the results of periodic management evaluations and annual independent registered public accounting firm attestation reports regarding the effectiveness of our internal control over financial reporting that we may be required to include in our periodic reports we will file with the SEC under Section 404 of the Sarbanes- Oxley Act, harm our operating results, cause us to fail to meet our reporting obligations or result in a restatement of our prior period financial statements. In the event that we are not able to demonstrate compliance with the Sarbanes- Oxley Act, that our internal control over financial reporting is perceived as inadequate or that we are unable to produce timely or accurate financial statements, investors may lose confidence in our operating results and the price of our common stock could decline. In addition, if we are unable to continue to meet these requirements, we may be unable to remain listed on Nasdaq. Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud. We are subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to provide reasonable assurance that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures, no matter how well- conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision- making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected. Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees. Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for state law claims for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty or other wrongdoing by any of our directors, officers, employees or agents to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the DGCL or our amended and restated certificate of incorporation or amended and restated bylaws or (iv) any action asserting a claim governed by the internal affairs doctrine, or the Delaware Forum Provision. The Delaware Forum Provision does not apply to any causes of action arising under the Securities Act or the Exchange Act. Our amended and restated bylaws further provides that unless we consent in writing to the selection of an alternative forum, the United States District Court for the District of Delaware will be the sole and exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, or the Federal Forum Provision, as the Company is incorporated in the State of Delaware. In addition, our amended and restated bylaws provides that 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 Delaware Forum Provision and the Federal Forum Provision; provided, however, that stockholders cannot and will not be deemed to have waived our compliance with the U. S. federal securities laws and the rules and regulations thereunder. We believe the Delaware Forum Provision and the Federal Forum Provision benefits us by providing increased consistency in the application of Delaware law by chancellors particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi- forum litigation. However, this provision 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 such lawsuits against us and our directors, officers and other employees and also may impose additional litigation costs on stockholders in pursuing any such claims. In addition, while the Delaware Supreme Court ruled in March 2020 that federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court are " facially valid " under Delaware law, there is uncertainty as to whether other courts will enforce our Federal Forum Provision. If the Federal Forum Provision is found to be unenforceable, we may incur additional costs associated with resolving such matters. The Federal Forum Provision may also impose additional litigation costs on stockholders who assert that the provision is not enforceable or invalid. The Court of Chancery of the State of Delaware and the United States District Court for the District of Delaware may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders. Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain. We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future. General Risk Factors Adverse developments affecting the financial services industry could adversely affect our current and projected business operations and our financial condition and results of operations. Adverse developments that affect financial institutions, such as events involving liquidity that are rumored or actual, have in the past and may in the future lead to bank failures and market- wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank (" SVB "), where we

held substantially all of our cash and cash equivalents, was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation (“ FDIC ”) as receiver. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each sent into receivership. The Department of the Treasury, the Federal Reserve and the FDIC released a statement that indicated that all depositors of SVB would have access to all of their funds, including funds held in uninsured deposit accounts, after only one business day of closure. As of March 13, 2023, we had access to all of our funds held at SVB. The U. S. Department of Treasury, FDIC and Federal Reserve Board have announced a program to provide up to $ 25 billion of loans to financial institutions secured by certain of such government securities held by financial institutions to mitigate the risk of potential losses on the sale of such instruments, widespread demands for customer withdrawals or other liquidity needs of financial institutions for immediately liquidity may exceed the capacity of such program. There is no guarantee, however, that the U. S. Department of Treasury, FDIC and Federal Reserve Board will provide access to uninsured funds in the future in the event of the closure of other banks or financial institutions, or that they would do so in a timely fashion. Uncertainty remains over liquidity concerns in the broader financial services industry, and our business, our business partners, or industry as a whole may be adversely impacted in ways that we cannot predict at this time. Although we assess our banking relationships as we believe necessary or appropriate, our access to cash in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect the financial institutions with which we have banking relationships, and in turn, us. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could also include factors involving financial markets or the financial services industry generally. The results of events or concerns that involve one or more of these factors could include a variety of material and adverse impacts on our current and projected business operations and our financial condition and results of operations. These could include, but may not be limited to, delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets; or termination of cash management arrangements and / or delays in accessing or actual loss of funds subject to cash management arrangements. In addition, widespread investor concerns regarding the U. S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our financial and / or contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity and our current and / or projected business operations and financial condition and results of operations. In addition, a critical vendor or business partner could be adversely affected by any of the liquidity or other risks that are described above as factors, which in turn, could have a material adverse effect on our current and / or projected business operations and results of operations and financial condition. Any business partner or supplier bankruptcy or insolvency, or any breach or default by a business partner or supplier, or the loss of any significant business partner or supplier relationships, could result in material adverse impacts on our current and / or projected business operations and financial condition. Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations. Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. ~~The~~ **Global economic and business activities continue to face widespread uncertainties, and** global **credit and** financial ~~crisis caused~~ **markets have experienced** extreme volatility and disruptions in the ~~capital~~ **past several years, including severely diminished liquidity** and credit ~~markets~~ **availability, rising inflation and monetary supply shifts, rising interest rates, labor shortages, declines in consumer confidence, declines in economic growth, increases in unemployment rates, recession risks, and uncertainty about economic and geopolitical stability** . A severe or prolonged economic downturn, such as the global financial crisis, could result in a variety of risks to our business, including weakened demand for our products, and our ability to raise additional capital when needed on acceptable terms, if at all. Supply chain disruptions ~~has~~ **have** lengthened our suppliers’ timelines and increased costs. The occurrence of, or acceleration or exasperation of, any of the foregoing could harm our business and we cannot anticipate all of the ways in which the economic climate and financial market conditions could adversely affect our business. Our internal computer systems, or those of any of our CROs, manufacturers, other contractors, consultants, existing or future collaborators, may fail or suffer security or data privacy breaches or other unauthorized or improper access to, use of or destruction of our proprietary and confidential data, employee data or personal data, which could result in additional costs, significant liabilities, harm to our reputation and material disruption of our operations. Despite the implementation of security measures, our internal computer systems and those of our current and any future CROs, other contractors, consultants, potential future collaborators and other third- party service providers are vulnerable to damage from various methods, including cybersecurity attacks, breaches, intentional or accidental mistakes or errors **, attacks using artificial intelligence** , or other technological failures, which can include, among other things, computer viruses, unauthorized access attempts, including third parties gaining access to systems using stolen or inferred credentials, denial- of- service attacks, phishing attempts, service disruptions, natural disasters, fire, terrorism, war and telecommunication and electrical failures. As the cyber- threat landscape evolves, these attacks are growing in frequency, sophistication and intensity, and are becoming increasingly difficult to detect. If such an event were to occur and cause interruptions in our operations or result in the unauthorized acquisition of or access to personally identifiable information or individually identifiable health information (violating certain privacy laws such as HIPAA,, or HITECH Act, the CCPA and GDPR), it could result in a material disruption of our product candidate development programs and our business operations, and we could incur significant liabilities. Some of

the federal, state and foreign government requirements include obligations of companies to notify individuals of security breaches involving particular personally identifiable information, which could result from breaches experienced by us or by our vendors or contractors. Notifications and follow- up actions related to a security breach could impact our reputation and cause us to incur significant costs, including legal expenses and remediation costs. For example, the loss of clinical trial data from completed, ongoing or future clinical trials involving our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the lost data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data, or inappropriate disclosure of confidential or proprietary information, we could be exposed to litigation and governmental investigations, the further development and commercialization of our product candidates could be delayed, and we could be subject to significant fines or penalties for any noncompliance with certain state, federal or international privacy and security laws. Our insurance policies may not be adequate to compensate us for the potential losses arising from any such disruption, failure or security breach. In addition, such insurance may not be available to us in the future on economically reasonable terms, or at all. Further, our insurance may not cover all claims made against us and could have high deductibles in any event, and defending a suit, regardless of its merit, could be costly and divert management attention. The estimates of market opportunity and forecasts of market growth that we provide may prove to be inaccurate, and even if the markets in which we compete achieve the forecasted growth, our business may not grow at similar rates, or at all. The market opportunity estimates and growth forecasts we provide are subject to significant uncertainty and are based on assumptions and estimates which may not prove to be accurate. The estimates and forecasts relating to size and expected growth of our target market may prove to be inaccurate. Even if the markets in which we compete meet the size estimates and growth forecasts, our business may not grow at similar rates, or at all. Our growth is subject to many factors, including our success in implementing our business strategy, which is subject to many risks and uncertainties. Our employees, independent contractors, consultants, commercial partners, collaborators and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements. We are exposed to the risk of employee fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners, collaborators, service providers and vendors. Misconduct by these parties could include intentional, reckless and / or negligent conduct that fails to comply with the laws of the FDA and other similar foreign regulatory bodies, provide true, complete and accurate information to the FDA and other similar foreign regulatory bodies, comply with manufacturing standards we have established, comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws, or report financial information or data accurately or to disclose unauthorized activities to us. ~~If~~ **As we begin commercializing our products and if** we obtain FDA approval of ~~any of~~ our product ~~candidates~~ **candidate** ~~and begin commercializing those products~~ in the United States, our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws will also increase. These laws may impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs. We have a code of business conduct and ethics and maintain a training program, but it is not always possible to identify and deter misconduct by our employees, independent contractors, consultants, commercial partners and vendors, and the precautions we take to detect and prevent this activity 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 comply with these laws or regulations. If any 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 civil, criminal and administrative penalties, damages, monetary fines, imprisonment, disgorgement, possible exclusion from participation in government healthcare programs, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of ~~non- compliance~~ **noncompliance** with these laws, contractual damages, reputational harm, diminished profits and future earnings and the curtailment of our operations. An active trading market for our common stock may not be sustained. We cannot assure you that an active trading market for our common stock will be sustained. The lack of an active trading market may impair the value of your shares and your ability to sell your shares at the time you wish to sell them. An inactive trading market may also impair our ability to raise capital by selling shares of our common stock and enter into strategic partnerships or acquire other complementary products, technologies or businesses by using shares of our common stock as consideration. Furthermore, there can be no guarantee that we will continue to satisfy the continued listing standards of Nasdaq. If we fail to satisfy the continued listing standards, we could be de- listed, which would have a negative effect on the price of our common stock. We expect that the price of our common stock will fluctuate substantially. The market price of our common stock has been highly volatile and may fluctuate substantially due to many factors, some of which are beyond our control, including: • announcements of regulatory approval or disapproval of our FemBloc system or the FDA' s decision to grant or decline ~~the de novo request for our FemaSeed product and~~ any future approvals or clearances for enhancements to our products; • adverse results from or delays in clinical ~~trials~~ **trial** of our FemBloc system ~~and / or FemaSeed product~~ ; • unanticipated safety concerns related to the use of our FemBloc system ~~and / or FemaSeed product~~ ; • FDA or other U. S. or foreign regulatory or legal actions or changes affecting us or our industry; • our ability to develop, obtain regulatory clearance or approval for, and market new and enhanced medical products on a timely basis; • any voluntary or mandated product recalls; • adverse developments concerning our suppliers or any future strategic partnerships; • the volume and timing of sales of our products; • the introduction of new products or product enhancements by us or others in our industry; • disputes or other developments with respect to our or others ~~'~~ **'** intellectual property rights; • product liability claims or other litigation; • quarterly variations in our results of operations or those of others in our industry; • media exposure of our products or of those of others in our industry; • changes in governmental regulations or in reimbursement; • changes in earnings estimates or recommendations by securities analysts; • changes in financial estimates or guidance, including our ability to meet our future revenue and operating profit or loss estimates or guidance; • the public' s reaction to our earnings releases, other public announcements and filings with the SEC; • sales of substantial amounts of our stock by directors,

officers or significant stockholders, or the expectation that such sales might occur; • operating and stock performance of other companies that investors deem comparable to us and overall performance of the equity markets; • additions or departures of key personnel; • changes in our capital structure, such as future issuances of securities and the incurrence of debt; • general market conditions and other factors, including factors unrelated to our operating performance or the operating performance of our competitors; and • other factors described in this " Risk Factors " section. In recent years, the stock markets generally have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. Broad market and industry factors may significantly affect the market price of our common stock, regardless of our actual operating performance. In addition, in the past, class action litigation has often been instituted against companies whose securities have experienced periods of volatility in market price. Securities litigation brought against us following volatility in our stock price, regardless of the merit or ultimate results of such litigation, could result in substantial costs, which would hurt our financial condition and operating results and divert management ~~'~~**'** s attention and resources from our business. Securities analysts may not continue to publish favorable research or reports about our business or may publish no information at all, which could cause our stock price or trading volume to decline. The trading market will be influenced to some extent by the research and reports that industry or financial analysts publish about us and our business. We do not control these analysts. **Our** ~~As a relatively new public company, we may be slow to attract~~ research coverage **may be inconsistent** and ~~the~~ **not as robust as larger and more established public companies and, as we begin to establish a commercialization operation,** analysts **may be unable** ~~who publish information about our common stock will have had relatively little experience with us or our industry, which could affect their ability~~ to accurately forecast our results and could make it more likely that we fail to meet their estimates. **If** ~~In the event we obtain securities or industry analyst coverage, if~~ any of the analysts who cover us provide inaccurate or unfavorable research or issue an adverse opinion regarding our stock price, our stock price could decline. If one or more of these analysts cease coverage of us or fail to publish reports covering us regularly, we could lose visibility in the market, which in turn could cause our stock price or trading volume to decline and result in the loss of all or a part of your investment in us. Item 1B. Unresolved Staff Comments.