Risk Factors Comparison 2024-03-28 to 2023-03-31 Form: 10-K

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Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below, together with all of the other information in this Annual Report, including our financial statements and related notes, which could have a material adverse effect on our business, financial condition, results of operations, and prospects. The risks described below are not the only risks facing us. Risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially affect our business, financial condition, results of operations, and prospects. In addition, any worsening of the economic environment may exacerbate the risks described below, any of which could have a material impact on us ~~. Summary Our business is subject to numerous risks and uncertainties that you should consider before investing in our common stock. These risks are described more fully below and include, but are not limited to, risks relating to the following: ● Our limited operating history and our limited revenue producing operations; ● Our inability to operate without additional fundraising; ● Our lack of experience developing and manufacturing medical products for cardiologists; ● Competition within our industry and in the markets and market segments we choose to pursue, including cardiology; ● Health epidemics, including the coronavirus pandemic; ● Our reliance on certain third parties, such as key suppliers; ● Potential loss of key management personnel and high employee attrition; ● Potential security breaches, loss of data, and other disruptions to us or to our third- party service providers that could compromise sensitive information; ● Potential product liability lawsuits and other litigation; ● The timing, unpredictability, and expense of our clinical and product development activities; ● The possibility of adverse clinical trial results and unfavorable long- term clinical trial data, especially given our limited pre- clinical experience using NPS technology in animal models of cardiac disease; ● Potential failure to obtain and maintain necessary regulatory clearances or approvals; ● Uncertainties concerning the long- term safety and effectiveness of our CellFX System and product candidates, and the potential for adverse side effects; ● The commercial uncertainties concerning whether there will be broad adoption of our CellFX System and NPS technology, especially in the cardiology market given our announced focus on cardiac care, and uncertainties about whether we will be able to secure a partner to promote further sales of the CellFX System in dermatology profitably; ● Possible challenges enrolling patients in our clinical trials; ● Uncertainties concerning our ability to obtain an adequate level of reimbursement by Medicare and other third- party payers; ● Protection of intellectual property, potential litigation related to intellectual property, and obligations under intellectual property agreements; ● Stringent domestic and foreign regulation in respect of any potential devices and products, including healthcare laws and regulations; 9 ● Healthcare policy changes; ● Volatility of the price of our common stock; ● Concentration of ownership by our principal stockholder and Executive Chairman, Robert W. Duggan; ● Potential material weaknesses and uncertainties concerning our ability to maintain an effective system of internal control over financial reporting; and ● Unfavorable global economic or political conditions~~ . Risks Relating to Our Business, Industry and Financial Condition Because we have a limited operating history and no significant revenue stream, it is difficult to evaluate the future of our business. We are a bioelectric medicine technology company with no significant revenue producing operations. To date, our operations on a consolidated basis have consisted almost entirely of the continued development and clinical studies of our technologies and implementation of the early parts of our business plan. We have incurred significant operating losses in each year since our inception and we may continue to incur additional losses for the next several years. In addition, a high percentage of our expenses will continue to be fixed; accordingly, our losses may be greater than expected and our operating results may suffer. We have limited historical financial data upon which we may base our projected revenue and base our planned operating expenses. Our limited operating history makes it difficult to evaluate our technology, operations, and business prospects. We have not generated significant revenue and we may never become profitable. To date, we have not generated significant revenue and we have historically relied on financing from the sale of equity securities and loans to fund our operations. We expect that our future financial results will depend primarily on our success in launching, selling, and supporting our therapies and procedures using our NPS technology. We expect to expend significant resources on hiring of personnel, continued scientific and product research and development, potential product testing and preclinical and clinical investigation, intellectual property development and prosecution, capital expenditures, working capital, general and administrative expenses, and fees and expenses associated with our capital raising efforts. We expect to incur costs and expenses related to consulting costs, laboratory development costs, hiring of scientists, engineers, sales representatives, and other operational personnel, and the continued development of relationships with potential partners. We are incurring significant operating losses, we expect to continue to incur additional losses for at least the next several years, and we cannot assure you that we will generate substantial revenue or be profitable in the future. There are no assurances that our future products will be cleared or approved or become commercially viable or accepted for use. Even with commercially viable applications of our technology, which may include licensing, we may never recover our research and development expenses. Investment in medical technology is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product will fail to demonstrate adequate efficacy or clinical utility. Our past successes in dermatology may not translate into similar results in cardiology **or elsewhere** . Investors should evaluate an investment in us in light of the uncertainties typically encountered by developing medical technology companies in a competitive environment ~~, especially given our limited preclinical experience using our NPS technology in animal models of cardiac disease~~ . There can be no assurance that our efforts will be successful, either in cardiology or otherwise, or that we will ultimately be able to achieve profitability. Even if we achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable could adversely affect the market price

of our common stock and could significantly impair our ability to raise capital, expand our business, or continue to implement our business plan. We can give no assurance that our internal and external sources of liquidity will be sufficient for our cash requirements. We must have sufficient sources of liquidity to fund our working capital requirements and execute on our strategic initiatives. Future new product launches or investments in other growth initiatives may demand increased working capital before any long- term return is realized from increased revenue. Our ability to achieve our business and cash flow plans is based on a number of assumptions which involve significant judgments and estimates of future performance, borrowing capacity and credit availability, and financing opportunities which cannot at all times be assured. ~~Additionally, in September 2022, to fund operations, we borrowed $ 65 million from our majority stockholder and Executive Chairman, Robert W. Duggan, and we will need to raise additional capital in order to repay this loan by no later than its maturity date in September 2024. Accordingly, there~~ **There** is no assurance that cash flows from operations and other internal and external sources of liquidity will at all times be sufficient for our cash requirements ~~, including repayment of the loan and other indebtedness~~. If necessary, we may need to consider actions and steps to improve our cash position and mitigate any potential liquidity shortfall, such as modifying our business plans, pursuing additional financing to the extent available, reducing capital expenditures, suspending certain activities or programs, pursuing and evaluating other alternatives and opportunities to obtain additional sources of liquidity, and other potential actions to reduce costs. There can be no assurance that any of these actions would be successful, sufficient or available on favorable terms. Any inability to generate or obtain sufficient levels of liquidity to meet our cash requirements at the level and times needed could have a material adverse impact on our business and financial position. ~~10If~~ **11If** we are unable to obtain sufficient funding, we may be unable to execute our business plan and fund operations. We may not be able to obtain additional financing on commercially reasonable terms, or at all. We have experienced operating losses and we ~~may~~ **expect to** continue to incur operating losses for the next several years as we implement our business plan. Currently, we have no significant revenue from operations and ~~, although we have implemented an at- the- market equity offering program,~~ we do not have arrangements in place for all the anticipated financing that would be required to fully implement our business plan. Our prior losses, combined with expected future losses, have had, and will continue to have, for the foreseeable future, an adverse effect on our stockholders' equity and working capital. We will need to raise additional capital in order to continue to execute our business plan. If we are unable to raise sufficient additional funds, we may need to scale back our future operations. Also, the ongoing **armed conflicts in** ~~hostilities between Russia and~~ Ukraine **, Israel** and **elsewhere, which have** ~~the ongoing COVID- 19 pandemic and resulting negative~~ **negatively** ~~impact~~ **impacted** ~~on~~ the global macroeconomic environment and capital markets **,** may make it more difficult for us to raise additional funds ~~. Also, the existing debt obligations we owe to our Executive Chairman may make future equity financings difficult to structure, more costly to the Company, and harder to complete, and additionally we may be required to incur more debt in the future~~. We cannot give any assurance that we will be able to obtain all the necessary funding that we may need. In addition, we believe that we will require additional capital in the future to fully develop and bring to market our technologies and planned products. We have pursued and may pursue additional funding through various financing sources, including the private sale of our equity securities, debt financings ~~, our at- the- market equity offering program~~, licensing fees for our technology, joint ventures with capital partners, and project type financing. If we raise funds by issuing equity or equity- linked securities, dilution to some or all our stockholders would result. Any equity securities issued may also provide for rights, preferences or privileges senior to those of holders of our common stock. The terms of debt securities issued or borrowings could impose significant restrictions on our operations. We also may seek government- based financing, such as development and research grants. There can be no assurance that funds will be available on commercially reasonable terms, if at all. Any future indebtedness could impose on us restrictive covenants, including, further limitations on our ability to incur additional debt, limitations on our ability to issue additional equity, limitations on our ability to acquire or license intellectual property rights, and other operating restrictions that could adversely affect our ability to conduct our business. In addition, the issuance of additional equity securities by us, or the possibility of such issuance, may cause the market price of our common stock to decline. Also, in the event that we enter into collaborations or licensing arrangements to raise capital, we may be required to accept unfavorable terms. These agreements may require that we relinquish, or license to a third party on unfavorable terms, our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves or reserve certain opportunities for future potential arrangements when we might otherwise be able to achieve more favorable terms. In addition, we may be forced to work with a partner on one or more of our products or market development programs, which could lower the economic value of those programs to us. If we are unable to obtain adequate financing or financing on terms satisfactory to us when we require it, we may be required to, among other things, delay, scale back or eliminate some or all of our activities, reduce headcount, trim research and product development programs, discontinue clinical trials, stop all or some of our manufacturing operations, defer capital expenditures, deregister from being a publicly traded company and delist from Nasdaq, or license our potential products or technologies to third parties, possibly on terms that cannot sustain our current business, or curtail, suspend or discontinue our operations entirely. If any of these things were to occur, our ability to grow and support our business and to respond to market challenges could be significantly limited or we may be unable to continue operations, in which case you could lose your entire investment. ~~Our~~ **Because our business is not profitable, from time to time, we may undergo a reduction in force to reduce our operating expenses. However, any** corporate restructuring **or** ~~and the associated~~ headcount reduction ~~announced in March and September 2022 and February 2023~~ may not result in anticipated savings, could result in total costs and expenses and attrition that are greater than expected and could disrupt our business. ~~On March 31, 2022, we announced an approximate 20 % reduction in headcount as part of a corporate restructuring plan. On September 30, 2022, we announced an approximate 40 % reduction in headcount as part of our decision to focus our activities on product development outside of dermatology.~~ As a consequence of our ~~announced~~ corporate realignment, we ~~have~~ experienced employee turnover in 2022 higher than industry norms, and in February 2023 we continued to reduce headcount by eliminating another seven positions at the Company. ~~We~~ **If we decide to further reduce headcount to**

lower our operating expenses, we may not realize, in full or in part, the anticipated benefits, savings and improvements in our cost structure from ~~our~~ **such a** restructuring **because of** ~~efforts due to~~ unforeseen difficulties, delays or unexpected costs. If we are unable to realize the expected operational efficiencies and cost savings from ~~the~~ **such a** restructuring ~~plan~~, our operating results and financial condition would be adversely affected. **Any** ~~We may have to undertake additional headcount reductions or~~ restructuring activities **would** ~~in the future. Furthermore, our restructuring activities may~~ be disruptive to our operations and could result in material delays in our new product development programs. **Also** ~~For example~~, ~~our~~ **any** headcount reductions could yield unanticipated consequences, such as attrition beyond planned staff reductions, or increase difficulties in our day- to- day operations ~~, servicing of commercial accounts, and product development activities~~. ~~Our headcount~~ **Headcount** reductions could also harm our ability to attract and retain qualified management, scientific, clinical, regulatory, manufacturing, engineering, and other personnel **who are** critical to our business. Any failure to attract or retain qualified personnel could prevent us from successfully developing and commercializing our new product candidates in the future ~~and could also harm our existing and planned commercial activities in dermatology~~. ~~11Because our business is not profitable, from time to time we may undergo a reduction in force to reduce our operating expenses. However, any corporate restructuring or headcount reduction may not result in anticipated savings, could result in total costs and expenses and attrition that are greater than expected and could disrupt our business. If we decide to further reduce headcount to lower our operating expenses, we may not realize, in full or in part, the anticipated benefits, savings and improvements in our cost structure from such a restructuring because of unforeseen difficulties, delays or unexpected costs. If we are unable to realize the expected operational efficiencies and cost savings from such a restructuring, our operating results and financial condition would be adversely affected. Any restructuring activities would be disruptive to our operations and could result in material delays in our new product development programs. Headcount reductions could yield unanticipated consequences, such as attrition beyond planned staff reductions, or increase difficulties in our day- to- day operations. Headcount reductions could also harm our ability to attract and retain qualified management, scientific, clinical, regulatory, manufacturing, engineering, and other personnel who are critical to our business. Any failure to attract or retain qualified personnel could prevent us from successfully developing and commercializing our new product candidates in the future. Our~~ **12Our** revenues and future profitability are entirely dependent upon one family of products, the CellFX System, and one platform technology, Nano- ~~Pulse~~ **pulse** Stimulation. Our revenue to date has been generated entirely from the CellFX System, which consists of a console, ~~handpieces~~ **connectors** and ~~tips~~ **end- effectors**, and ~~both~~ these products and all our potential products under development are based upon the same patented platform technology, Nano- ~~Pulse~~ **pulse** Stimulation (" NPS "). Our future revenue is therefore dependent on the success of these products under development and platform technology. Reliance on a single family of products and single platform technology could negatively affect our results of operations and financial condition. Our ability to become profitable will depend upon the commercial success of these future products and platform technology. **In 2021 to 2022,** ~~Aesthetic~~ **aesthetic** and medical dermatologists **were** ~~have been~~ slow to adopt our products and **even today** they have used our products in only a small percentage of their eligible patients ~~for a variety of reasons~~. Even if we are able to develop a safe and effective treatment for atrial fibrillation using our proprietary NPS technology, we can give no assurance that cardiologists would adopt NPS technology into their medical practices faster than dermatologists have. **We intend to market the CellFX nsPFA Percutaneous Electrode System primarily to Otolaryngologists, Endocrine Surgeons, and Interventional Radiologists (" surgeons ") who may be slow or fail to adopt our products or who may use our products in only a small percentage of their eligible patients for a variety of reasons, including but not limited to: ● lack of experience with our products; ● lack of adequate reimbursement or cost to the patient; ● lack of conviction regarding evidence supporting cost benefits or cost effectiveness of our products over existing alternatives; ● lack of clinical data showing longer- term patient benefits; ● the possible introduction of new technologies competitive to our products; and ● liability risks generally associated with the use of new products and procedures. Moreover, our products, including our platform NPS technology, could be rendered obsolete or economically impractical by numerous factors, many of which are beyond our control, including but not limited to: ● entrance of new competitors into our markets; ● technological advancements of alternative technologies; ● loss of key relationships with suppliers, group purchasing organizations, or end- user customers; ● manufacturing or supply interruptions; ● product liability claims; ● our reputation and product market acceptance; ● loss of existing regulatory approvals or the imposition of new requirements to maintain such approvals or to receive new approvals; and ● product recalls or safety alerts. 13We may fail to meet our publicly announced guidance or other expectations about our business and future operating results, which could cause our stock price to decline. The Company may, from time to time, provide financial guidance about its business and future operating results. In developing this guidance, the Company' s management must make certain assumptions and judgments about its future operating performance, including but not limited to projected hiring of sales professionals, growth of revenue in the relevant device markets, increase or decrease of its market share, costs of production of its recently introduced products, and stability of the macro- economic environment in the Company' s key markets. Furthermore, analysts and investors may develop and publish their own projections of the Company' s business, which may form a consensus about the Company' s future performance. The Company' s business results may vary significantly from such guidance or that consensus due to a number of factors, many of which are outside of the Company' s control, and which could adversely affect its operations and operating results. Furthermore, if the Company makes downward revisions of its own previously announced guidance, or if the Company' s publicly announced guidance of future operating results fails to meet expectations of securities analysts, investors or other interested parties, the price of the Company' s common stock could decline. Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations. Our quarterly and annual operating results may fluctuate significantly, which makes it difficult for us to predict our future operating results. These fluctuations may occur due to a variety of factors, many of**

which are outside of our control and may be difficult to predict, including: ● the timing and cost of, and level of investment in, research, development, and commercialization activities relating to our product and product candidates, which may change from time to time; ● the timing of receipt of approvals or clearances for our product candidates from regulatory authorities internationally or in the United States, such as the U. S. FDA; ● the timing and status of enrollment for our clinical trials; ● coverage and reimbursement policies with respect to our product and product candidates, including the degree to which procedures using our products are covered and receive adequate reimbursement from third- party payors, and potential future drugs or devices that compete with our products; ● the costs of manufacturing our products, as well as building out our supply chain, which may vary depending on the quantity of production and which will vary significantly depending upon the terms of our agreements with manufacturers; ● expenditures that we may incur to acquire, develop or commercialize additional product candidates and technologies; ● the level of demand for our product and any product candidates, if approved or cleared, which may vary significantly over time; ● litigation, including patent, employment, securities class action, stockholder derivative, general commercial, and other lawsuits; ● future accounting pronouncements or changes in our accounting policies; and ● the timing and success or failure of nonclinical studies and clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners. The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period- to- period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met our previously publicly stated revenue or earnings guidance. ~~Because~~ **14Because** we operate in highly competitive markets, we can expect to face competition from large ~~,~~well- established manufacturers of medical technologies, devices and similar products; we may not be able to compete effectively against companies with significantly more resources. The medical technology, medical device, biotechnology, and pharmaceutical industries are characterized by intense and dynamic competition to develop new technologies and proprietary therapies. We face competition from a number of sources, such as pharmaceutical companies, medical device companies, generic drug companies, biotechnology companies, and academic and research institutions. For example, Abbott Laboratories, AtriCure, Inc., Boston Scientific Corporation, Johnson & Johnson (Biosense Webster), Medtronic plc, and several other companies all sell ablation-based surgical and catheter- based medical devices for the treatment of heart arrhythmias, including AF, and additionally, many of these companies are also actively developing PFA products for the treatment of AF. We will find ourselves in competition with one or more of these companies, all of which may have competitive advantages over us, such as: ● significantly greater name recognition; ● established relationships with healthcare professionals, customers, and third- party payers; ● competitive products with greater efficacy or better safety profiles; ● established distribution networks; ● additional lines of products and the ability to offer rebates, higher discounts, or incentives to gain a competitive advantage; ● greater experience in obtaining patents and regulatory approvals for product candidates; ● greater experience conducting new product research and development, manufacturing therapies, conducting clinical trials, obtaining regulatory approval for products, and marketing approved products; and ● greater financial and human resources for product development, sales and marketing. We may also face increased competition in the future as new companies enter our markets and as scientific developments surrounding electro-signaling therapeutics continue to accelerate. For example, the current standard of care in cardiac tissue ablation for the treatment of atrial fibrillation is the use of thermal ablation modalities, primarily the use of radiofrequency ablation. While we will seek to expand our technological capabilities to remain competitive, research and development by others may render our technology or product candidates obsolete or noncompetitive or result in treatments or cures superior to any therapy developed by us. ~~In dermatology~~ **We may rely on third parties for our sales** , **marketing, manufacturing, and / or distribution activities, and these third parties may not perform satisfactorily. To be able to commercialize our products and planned products,** we **may elect to internally develop aspects of sales, marketing, large- scale manufacturing, or distribution, or we may elect to use third parties with respect to one or more of these functions. Our reliance on these third parties may reduce our control over these functions; however, reliance on third parties does not relieve us of our responsibility to ensure compliance with all required legal, regulatory, and scientific standards. Any failure of these third parties to perform satisfactorily and in compliance with relevant laws and regulations could lead to delays in the development of our products or planned products, including delays in our clinical trials, or failure to obtain necessary regulatory approvals, or failure to successfully commercialize our products or other future products. Some of these events could be the basis for FDA or other regulatory action, including injunction, recall, seizure, or total or partial suspension of production. We have recently** commenced revenue- producing operations ~~in 2021~~ ; however, we ~~have been~~ **may be** unsuccessful in earning significant revenues. We ~~therefore intend to~~ **believe that developing the commercialization aspects of a company will take a substantial amount of capital and commitment of time and effort. We may** seek development and marketing partners and license our technology to others in order to avoid **our** having to provide **the** marketing, manufacturing, and distribution capabilities within our organization. There can be no assurance that we will find any development and marketing partners or companies that are interested in licensing our technology. **If we are unable to establish and maintain adequate sales, marketing, manufacturing, and distribution capabilities, independently or with others, we will not be able to generate product revenue, and may not become profitable.** ~~12If~~ **15If** we lose key management personnel, our ability to identify, develop and commercialize new or next generation product candidates will be impaired, could result in loss of

markets or market share and could make us less competitive. We are highly dependent upon the principal members of our management team, including our Chief Executive Officer, Kevin Danahy, and our Chief Technology Officer, Darrin Uecker, and members of our ~~finance,~~ scientific and engineering teams. These persons have significant experience and knowledge with sub- microsecond pulsed electric fields and more broadly in life sciences and medical technologies. The loss of any team member could impair our ability to design, identify, and develop new intellectual property and new scientific or product ideas. The loss of a key employee, the failure of a key employee to perform in his or her current position, or our inability to attract and retain skilled employees could result in our inability to continue to grow our business or to implement our business strategy. We compete for qualified management and scientific personnel with other life science companies, academic institutions, and research institutions. Our employees could leave our Company with little or no prior notice. They are free to work for a competitor. If one or more of our senior executives or other key personnel were unable or unwilling to continue in their present positions, we may not be able to replace them easily or at all, and other senior management may be required to divert attention from other aspects of the business. In addition, we do not have " key person " life insurance policies covering any member of our management team or other key personnel. The loss of any of these individuals or any inability to attract or retain qualified personnel, including scientists, engineers, and others, could prevent us from pursuing collaborations and materially and adversely affect our product development and introductions, business growth prospects, results of operations, and financial condition. There is a limited talent pool of experienced professionals in our industry. If we are not able to retain and recruit personnel with the requisite technical skills, we may be unable to successfully execute our business strategy. The specialized nature of our industry results in an inherent scarcity of experienced personnel in the field. Our future success depends upon our ability to attract and retain highly skilled personnel, including scientific, technical, commercial, business, regulatory, and administrative personnel, necessary to support our anticipated growth, develop our business and perform certain contractual obligations. Given the scarcity of professionals with the scientific knowledge we require and the intense competition that exists for qualified personnel among life science businesses, we may not succeed in attracting or retaining the personnel we require to continue and grow our operations. We have very limited experience selling the CellFX System. Successfully commercializing medical devices such as ours is a complex and uncertain process. We began marketing and selling the CellFX System in the United States, Canada, and certain limited European markets in late 2021 to dermatologists through a limited direct sales force. **In January 2022, we established an operating company in the Netherlands to further enhance our operations in Europe.** However, **in 2022 and 2023** we **eliminated all of our full- time sales and marketing positions and, as of December 31, 2023, we had no U. S. or international sales force. We** have ~~had~~ **only just recently begun to hire employees to help market and sell our CellFX nsPDA Percutaneous Electrode System. As of March 2024, our U. S. sales and marketing team consisted of just two employees, a Vice President focusing on the surgical ablation market and a Global Senior Director focusing on the minimally invasive surgery market. We therefore have** limited experience marketing and selling the CellFX System ~~in dermatology, no sales experience in cardiology,~~ and our revenues and cash flows have been volatile and difficult to predict. ~~As~~ **We intend to hire and train a very limited number** of ~~March 1~~ **sales representatives and clinical specialists with backgrounds and experience in the relevant markets** , ~~2023~~ **especially those familiar with energy- based therapies and who have existing relationships with dermatologist. However** , **we expect that our sales force will require lead time in the field to grow their network of accounts and achieve the productivity levels we expect them to reach in any individual territory. Furthermore, the use of our product will often require or benefit from direct support from us. Our commercialization efforts depend on the efforts of our management and sales team, our third- party manufacturers and suppliers, physicians and medical clinics, and general economic conditions, among other factors, including the** following **: ● the effectiveness of our marketing and sales efforts in the United States and internationally; ● our success in educating surgeons and other physicians and patients about the benefits, administration and use of our products; ● the acceptance by physicians and patients of the safety and effectiveness of our products; ● the availability, perceived advantages, relative cost, relative safety, and relative efficacy of alternative and competing therapies; and ● our ability** ~~two~~ **to** ~~reductions~~ **achieve and maintain compliance with all regulatory requirements applicable to our products. While few** in **number, we expect our direct sales representatives to develop long- lasting relationships with the surgeons they serve. Our future success will depend largely on our ability to continue to hire, train, retain and motivate skilled direct sales representatives with significant technical knowledge in various areas, such as cardiology, minimally invasive surgery, and ablation technologies. New hires require training and take time to achieve full productivity. If we fail to train new hires adequately, or if we experience high turnover in our sales** force in ~~2022 and a~~ **the future, we cannot be certain that new hires will become as productive as may be necessary to maintain or increase our sales. Also, if our direct sales representatives or** third ~~elimination of positions in February 2023~~ **- party distributors fail to adequately promote** , ~~we no longer had any employees engaged in~~ **market and sell our products or decide to leave or cease to do business with us, our** sales ~~and~~ **could significantly decrease or grow at a rate too slow to become profitable. In addition, our future sales will largely depend on our ability to increase our** marketing ~~activities on a fulltime basis~~ **efforts and adequately address our customers' needs. If we are unable to adequately address our customers' needs, it could negatively impact sales and market acceptance of our products, and we may not generate sufficient revenue to become profitable. If we are unable to expand our sales and marketing capabilities domestically and internationally, we may not be able to effectively commercialize our products, which would adversely affect our business, results of operations, and financial condition** . Rapidly changing technology in life sciences could make the products we are developing obsolete. The life sciences industries are characterized by rapid and significant technological changes, frequent new product introductions and enhancements, and evolving industry standards. Our future success will depend on our ability to continually develop and then improve the products that we design and to develop and introduce new products that address the evolving needs of our customers on a timely and cost- effective basis. Also, we will need to pursue new market opportunities that develop as a result of technological and

scientific advances. These new market opportunities may be outside the scope of our proven expertise or in areas which have unproven market demand. Any new products developed by us may not be accepted in the intended markets. Our inability to gain market acceptance of new products could harm our future operating results. **16If we are unable to manage the anticipated growth of our business, our future revenue and operating results may be harmed. From time to time, we have experienced rapid growth in our business. Recent and future growth imposes significant added responsibilities on management, including the need to identify, recruit, train, and integrate additional employees. Rapid expansion in personnel could mean that fewer experienced people carry out our research and development activities, manufacture, market, and sell CellFX Systems and NPS therapies and procedures, which could result in inefficiencies and unanticipated costs, reduced quality, and disruptions to our operations. In addition, rapid and significant growth may strain our administrative and operational infrastructure, and the failure to continue to upgrade our technical, administrative, operating, and financial control systems, or the occurrence of other unexpected expansion difficulties, could have a material adverse effect on our business, financial condition and results of operations, and our ability to timely execute our business plan.** We **may be unable to maintain the quality of, or delivery timelines of, our products or satisfy customer demand as it grows. Our ability to manage our growth properly will require us to continue to improve our operational, financial and management controls, as well as our reporting systems and procedures. We may implement new enterprise software systems in a number of areas affecting a broad range of business processes and functional areas. The time and resources required to implement these new systems is uncertain and failure to complete this in a timely and efficient manner could harm our business. We cannot guarantee that any of the personnel, systems, procedures, and controls we put in place will be adequate to support the manufacture and distribution of our products. If we** are ~~subject~~ **unable** to **manage our growth effectively** ~~laws and regulations relating to personally identifiable health information~~ **, it may be difficult for us to execute our business strategy and our business could be harmed. We must successfully educate and train surgeons and their staff on the proper use of the CellFX System; if our customers do not adopt our technology into their medical practices, or adopt our technology slower than expected, our business could suffer. Although most surgeons may have adequate knowledge on how to use our novel CellFX System based on their clinical training and experience, we believe that the most effective way to introduce and build market demand for our products is by directly training surgeons** and other **physicians in the use** ~~sensitive information. Security breaches, loss~~ of ~~data~~ **our products. Convincing them to dedicate the time and energy necessary for adequate training is challenging, and we cannot assure you that we will succeed in these efforts. If surgeons** and other ~~disruptions to~~ **physicians are not properly trained, they may not use our products and, as a result, we may not maintain or grow our sales or achieve or sustain profitability. If surgeons and other physicians are not properly trained, they may also misuse or ineffectively use our products, which may result in unsatisfactory patient outcomes, patient injury, negative publicity, or lawsuits against** us **, any of which could have a significant adverse effect on** ~~or~~ **our business, financial condition and results of operations. Additionally, our strategy includes educating key opinion leaders in the industry. If these key opinion leaders determine that alternative technologies are more effective** ~~our~~ **or that the benefits offered by our products are not sufficient to justify their higher cost, or if we encounter difficulty promoting adoption or establishing these systems as a standard of care, our ability to achieve market acceptance of the products we introduce could be significantly limited and our business could suffer. We may encounter manufacturing problems or delays that could result in lost revenue or slower than anticipated product development. Additionally, we currently rely on** third- party **suppliers** for critical materials needed to manufacture the CellFX System and related applicators.Any problems experienced by these suppliers could result in a delay or interruption of their supply to us and,as a result,we may face delays in the development and commercialization of products.We currently rely upon third- party suppliers to manufacture and supply components for the CellFX System and for our products under development.We perform final assembly of our CellFX devices at our facility in California.The manufacture of the CellFX components in compliance with the FDA' s regulations requires significant expertise and capital investment,including the development of advanced manufacturing techniques and process controls.Manufacturers of medical ~~device service~~ **device** products often encounter difficulties in production,including difficulties with production costs and yields,quality control,quality assurance testing,shortages of qualified personnel,as well as compliance with applicable regulations,both foreign and domestic.We do not control the manufacturing process of,and are completely dependent on,our contract manufacturing partners for compliance with applicable regulatory requirements,and if our contract manufacturers cannot successfully manufacture the components needed for our products and products under development in a manner that conforms to our specifications and these strict regulatory requirements,we may not be able to rely on their manufacturing facilities in the future.In addition,we have limited control over the ability of our contract manufacturers to maintain adequate quality control,quality assurance and qualified personnel.If the FDA or a comparable foreign regulatory authority finds these facilities inadequate for the manufacture of our components or if such facilities are subject to enforcement action in the future or are otherwise inadequate with respect to complying with applicable regulatory requirements,we may need to find alternative manufacturing facilities,which would significantly impact our ability to develop and market our product or to obtain regulatory approval or clearance for our product candidates.We currently purchase components for our products under development under purchase orders and do not have long- term contracts with most of the suppliers of these materials.If suppliers were to delay or stop producing our components,or if the prices they charge us were to increase significantly,or if they elected not to sell to us,we would need to identify other suppliers and we may not be able to secure alternative suppliers on favorable terms,or at all.Also,any number of our suppliers may be adversely impacted by COVID- 19 which could affect their ability to perform satisfactorily.Any failure of these suppliers to perform satisfactorily could adversely impact our business and results of operations and we may experience delays in manufacturing of our devices while finding another acceptable supplier. ~~We~~ **17We** may not become commercially viable if our ultimate commercialized products or related treatments fail to obtain an adequate

level of reimbursement by Medicare and other third- party payers.We believe that the commercial viability of the CellFX System and any potential devices and products and related treatments,and therefore our commercial success as a company,may be affected by the availability of government reimbursement and medical insurance coverage and reimbursement for newly approved medical therapies,technologies,and devices.Insurance coverage and reimbursement are not assured.It typically takes a period of use in the marketplace before coverage and reimbursement are granted,if it is granted at all.In the United States and in many other jurisdictions, **surgeons and other** physicians and other healthcare ~~providers generally rely~~ providers **generally rely on insurance coverage and reimbursement** ~~could compromise sensitive information related to our business or~~ **for** ~~prevent us from accessing critical information~~ **their revenues, therefore this is** ~~and~~ **an** ~~expose~~ **important factor in the overall commercialization plans of a proposed product and whether it will be accepted for** ~~us~~ **use in the marketplace. Without insurance coverage and reimbursement for our planned products, we would expect** to ~~liability~~ **earn only diminished revenues, if any revenues are earned. Medicare, Medicaid, health maintenance organizations, and other third- party payers are increasingly attempting to contain healthcare costs by limiting both the scope of coverage and the level of reimbursement of new medical technologies and products. As a result, they may not cover or provide adequate payment for the use of the CellFX System or planned products in development. In order to obtain satisfactory reimbursement arrangements, we may have to agree to reduce our fee or sales price below what we currently expect to charge customers** , which could adversely affect our ~~business~~ **profit margins. Moreover, each plan may separately require us to provide scientific** and **clinical support for the use of our products and, as a result, the coverage determination process is often a time- consuming and costly process with no assurance that coverage and adequate reimbursement will be applied consistently** ~~our~~ **or** ~~reputation~~ **obtained at all** . ~~In~~ **Even if Medicare and** ~~the~~ **other** ~~ordinary course of our business, both we and our~~ third- party **payers decide** ~~service providers may collect and store sensitive data, including legally protected health information, personally identifiable information about our patients, information related~~ to **cover procedures involving the CellFX** ~~our trials, intellectual property, and our proprietary business and financial information. We manage and maintain our applications and data using a combination of on- site and vendor- owned systems~~ **System** ~~. We face a number of risks related to our protection of,~~ and our **proposed devices** ~~service providers' protection of, this critical information, including loss of access to data, data corruption, unauthorized disclosure of data,~~ and **products** ~~unauthorized access of data~~ , ~~as~~ **we cannot be certain that the reimbursement levels** ~~well~~ **will be adequate. Accordingly,** ~~as risks associated with our ability to identify and audit such events~~ -- **even** ~~. 13We~~ **if these products** are **approved for commercial sale** ~~subject to environmental regulations and any failure to comply with applicable laws could subject us to significant liabilities and harm our business. We are subject to a variety of local~~ , **unless** ~~state, federal, and foreign~~ government ~~regulations relating to the storage, discharge, handling, emission, generation, manufacture,~~ and ~~disposal of toxic or~~ other ~~hazardous substances used in the manufacture of our products. The failure to comply with past, present or future laws could result in the imposition of fines,~~ third- party ~~property damage~~ **payers provide adequate coverage** and ~~personal injury~~ **reimbursement for our devices and products, some surgeons and other physicians may be discouraged from using them, and our sales would suffer. Medicare reimburses for medical technologies and products in a variety of ways, depending on where and how the item is used. However, Medicare only provides reimbursement if CMS determines that the item should be covered and that the use of the device or product is consistent with the coverage criteria. A coverage determination can be made at the local level by the Medicare administrative contractor, a private contractor that processes and pays** claims **on behalf** ~~, investigation and remediation costs, the suspension~~ of **CMS** ~~production, or~~ **for** ~~a cessation of operations. We also expect that~~ **the geographic area where the services were rendered,** ~~our~~ -- **or** ~~operations~~ **at the national level by CMS through a national coverage determination. There are statutory provisions intended to facilitate coverage determinations for new technologies, but it is unclear how these new provisions** will be **implemented,** ~~affected by other new environmental and health and safety laws on an~~ **and it is not possible to indicate how** ~~ongoing basis. Although we cannot predict the ultimate impact of any such new laws,~~ they **might apply** will likely result in additional costs,..... that may or may not be related to the CellFX System or **to any of** our ~~NPS~~ **proposed devices and products, as they are still in the development stages. Coverage presupposes that the** technology **, device, or product has been cleared or approved by the FDA and further, that the coverage will be consistent with the approved intended uses of the device or product as approved or cleared by the FDA, but coverage can be narrower** . ~~Such events could~~ **A coverage determination may be so limited that relatively few patients will qualify for a covered use of a device or product. Obtaining a coverage determination, whether local or national, is a time- consuming, expensive and highly uncertain proposition, especially for a new technology, and inconsistent local determinations are possible. On average, Medicare coverage determinations for medical devices and products lag behind FDA approval or clearance. The Medicare statutory framework is also** subject ~~us~~ to ~~costly litigation~~ **administrative rulings** , **interpretations and discretion** ~~require us to pay substantial amounts of money to injured patients, delay, negatively impact, or end our opportunity to receive or maintain regulatory approval to market those products, or require us to suspend or abandon our commercialization efforts. Even in a circumstance in which we do not believe~~ that **affect the amount** ~~an~~ **and** ~~adverse event~~ **timing of reimbursement made under Medicare. Medicaid coverage determinations and reimbursement levels are determined on a state- by- state basis, because Medicaid, unlike Medicare,** is **administered by** ~~related to our product, the investigation into the circumstance may be time consuming or inconclusive. These investigations may interrupt our sales efforts, delay our regulatory approval processes, or impact and limit the type of regulatory approvals our products could receive or maintain. As a result of these~~ -- **the** ~~factors,~~ **states under** a **state plan filed with the Secretary of the U** ~~product liability claim, even if successfully defended, could harm our business~~ . ~~We currently maintain product liability insurance~~ **S. Department of Health and Human Services (" HHS "). Medicaid generally reimburses at lower levels than Medicare. Moreover, Medicaid programs and private insurers are frequently influenced by Medicare** coverage **determinations** , ~~which may not be adequate to cover all liabilities that we may incur. Insurance coverage is increasingly expensive. We may not be able to~~

~~maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise~~ . Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited. We have incurred net losses since our inception and anticipate that we may continue to incur significant losses for the foreseeable future. If not utilized, some of our federal and state net operating losses (" NOLs ") carryforwards will begin to expire in various years beginning after 2034. Under the Internal Revenue Code of 1986, as amended, or the Code, and certain similar state tax provisions, we are generally allowed to carry forward our NOLs from a prior taxable year to offset our future taxable income, if any, until such NOLs are used or expire, subject to certain limitations. The same is true of other unused tax attributes, such as tax credits. ~~14In~~ **In** addition, under Section 382 of the Code, a corporation that undergoes an " ownership change " is subject to limitations on its ability to utilize its pre- change NOLs to offset future taxable income. We believe that we have had one or more ownership changes, and, as a result, a portion of our existing NOLs may be subject to limitation. Future changes in our stock ownership could result in additional limitations. We may not be able to utilize a material portion of our NOLs even if we attain profitability. We have a substantial amount of goodwill and intangible assets which over time may have to be written down as we make the required periodic assessments as to their value as reflected in our financial statements. A significant portion of our total assets are comprised of goodwill and intangibles that arose from our 2014 business acquisitions. We review goodwill for impairment at least annually or whenever changes in circumstances indicate that the carrying value of the goodwill may not be recoverable. We also review our intangible assets for impairment at each fiscal year end or when events or changes in circumstances indicate the carrying value of these assets may exceed their current fair values. If we take an impairment charge for either goodwill or intangible assets, the overall assets will be reduced. Such an impairment charge may result in a change in the perceived value of the Company and ultimately may be reflected as a reduction in the market price of our securities. Additionally, an impairment charge may also adversely influence our ability to raise capital in the future. ~~Risks~~ **18Risks** Related to Product Development Our CellFX System and any future product candidates may cause serious adverse side effects or have other properties that could delay or prevent their regulatory approval,limit their commercial desirability or result in significant negative consequences.The risk of failure of clinical development is high.For example,the vast majority of our in vivo data has been a result of animal testing outside of cardiac animal models,and we have only completed a limited number of feasibility studies in humans, ~~most~~ **all** of which have examined the use of our CellFX System in dermatologic conditions.Undesirable side effects caused by the CellFX System,NPS pulses,or any of our planned future products could cause us,any partners ~~of ours~~ ,or regulatory authorities to interrupt,delay or halt clinical trials or to revoke previously granted regulatory approvals.Undesirable side effects could also result in more restrictive labeling requirements or the delay or denial of regulatory approval of planned future products by the FDA or other comparable foreign regulatory authority.Additionally,if we or others identify undesirable side effects caused by the CellFX System,a number of potentially significant negative consequences could result,including:● we may be forced to recall such product and suspend the marketing of such product;● regulatory authorities may withdraw their approvals of such product;● regulatory authorities may require additional warnings on the label and / or narrow the indication of use for the product which could diminish the usage or otherwise limit the commercial success of such product;● the FDA or other regulatory authorities may issue safety alerts," Dear Healthcare Provider " letters,press releases,or other communications containing warnings about such product;● the FDA may restrict distribution of our product and impose burdensome implementation requirements on us;● we may be required to change the way the product is administered or conduct additional clinical trials;● we could be sued and held liable for harm caused to subjects or patients;and ● our reputation could suffer.Any of these events could prevent us from achieving or maintaining market acceptance of the CellFX System or of any future particular planned product,if approved **.We** Clinical development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure or delay can occur at any time during the clinical trial process. For example, success in nonclinical studies and early feasibility clinical studies does not ensure that the expanded clinical trials needed to support regulatory submissions will be successful. Setbacks can be caused by, among other things, nonclinical findings made while clinical trials are underway, safety or efficacy observations made in clinical trials, including previously unreported adverse events, or post- approval observations. Even if our clinical trials are completed, the results may not be sufficient to obtain regulatory approval or clearance for our product candidates or to expand the existing approvals or clearances for our existing products. To date, we have had **only** ~~very limited~~ preclinical experience using NPS technology in animal models of cardiac disease **and very limited clinical experience treating AF with our CellFX nsPFA 360 ° Cardiac Catheter** ; our past successes in dermatology may not translate into similar results in cardiology. In particular, the safety and efficacy data we have generated using NPS technology and the CellFX System to treat benign lesions in the skin **and the preliminary feasibility results we have seen in benign thyroid nodules** might not be replicated in other areas of medicine ~~outside of dermatology~~ , including the use of **CellFX** nsPFA technology and the CellFX System to treat atrial fibrillation or other cardiac disease. ~~Our~~ **19Our** long- term growth depends on our ability to develop marketable products to treat AF through our research and development efforts, and if we fail to do so we may be unable to compete effectively or we may decide to scale back or eliminate some or all of our activities or otherwise curtail, suspend or discontinue our operations entirely. The medical device industry is characterized by intense competition, rapid technological changes, new product introductions and enhancements, and evolving industry standards. Our business prospects depend in part on our ability to develop new products and applications for our NPS technology, including in new markets that develop as a result of technological and scientific advances. New technologies, techniques or products could emerge that might offer better combinations of price and performance than our products. It is important that we anticipate changes in technology and market demand, as well as physician, hospital, and healthcare provider practices to successfully develop, obtain clearance or approval, if required, and successfully introduce new, enhanced and competitive technologies to meet our prospective customers' needs on a timely and cost- effective basis. ~~We might be unable to successfully commercialize our current products with domestic or international regulatory clearances or approvals~~

~~or develop or obtain regulatory clearances or approvals to market new products, either with or without a corporate partner in cardiology, for example. Additionally, despite our best efforts and the best efforts of any corporate partners we may secure, these products and any future products might not be accepted by dermatologists, cardiologists, or other health care workers or the third- party payors who reimburse for the procedures performed with our products or may not be successfully commercialized due to other factors. The success of any new product offering or enhancement to an existing product will depend on numerous factors, including our ability to: ● properly identify and anticipate clinician and patient needs; ● develop and introduce new products or product enhancements in a timely manner; ● adequately protect our intellectual property and avoid infringing upon the intellectual property rights of third parties; ● demonstrate the safety and efficacy of new products; and ● obtain the necessary regulatory clearances or approvals for new products or product enhancements.~~ If we do not develop and obtain regulatory clearances or approvals for new products or product enhancements in time to meet market demand, or if there is insufficient demand for these products or enhancements, our results of operations will suffer. Our research and development efforts may require a substantial investment of time and resources before we are adequately able to determine the commercial viability of a new product, technology, material, or other innovation. In addition, even if we are able to develop enhancements or new generations of our products successfully, these enhancements or new generations of products may not produce sales in excess of the costs of development and they may be quickly rendered obsolete by changing customer preferences or the introduction by our competitors of products embodying new technologies or features. Moreover, if our technology cannot be used to successfully treat AF, we may decide to, among other things, delay, scale back or eliminate some or all of our activities, reduce headcount, trim research and product development programs, discontinue clinical trials, stop all or some of our manufacturing operations, defer capital expenditures, deregister from being a publicly traded company and delist from Nasdaq, or license our potential products or technologies to third parties, possibly on terms that cannot sustain our current business, or curtail, suspend or discontinue our operations entirely. ~~15Interim~~ **Interim** " top- line " and preliminary results from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data. From time to time, we may publish interim top- line or preliminary results from our clinical trials. Interim results from clinical trials that we may announce are subject to the risk that one or more of the clinical outcomes may materially change as **more follow- up data are gathered,** patient enrollment continues and more patient data become available. Preliminary or top- line results **, including our preliminary data from our feasibility thyroid nodule study,** 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 **or announced** . As a result, interim and preliminary data should be viewed with caution until the final data are available. Differences between preliminary or interim data and final data could significantly harm our business prospects and may cause the trading price of our common stock to fluctuate significantly. If we fail to maintain necessary regulatory clearance for our product, or if clearances or approvals for future devices and indications are delayed or not issued, the commercial prospects for our CellFX System and other NPS technologies would be harmed. Our product candidates under development are medical devices that are subject to extensive regulation by the FDA in the United States and by regulatory agencies in other countries where we do business. Government regulations specific to medical devices are wide- ranging and govern, among other things: ● device design, development and manufacture; ● laboratory, preclinical and clinical testing, labeling, packaging, and storage; ● premarketing clearance or approval; ● record keeping; ● device marketing, promotion and advertising, sales and distribution; and ● post- marketing surveillance, including reporting of deaths and serious injuries and recalls and correction and removals. Before a new medical device, or a new intended use for an existing device, can be marketed in the United States, the device' s manufacturer must first submit and receive either 510 (k) clearance or Premarket Approval (" PMA ") from the FDA, unless an exemption applies. In the 510 (k)- clearance process, the FDA will determine that a proposed device is " substantially equivalent " to a device legally on the market, known as a " predicate " device, with respect to intended use, technology and safety and effectiveness, in order to clear the proposed device for marketing. Clinical data is sometimes required to support substantial equivalence. The PMA pathway requires an applicant to demonstrate reasonable safety and effectiveness of the device based 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. Products that are approved through a PMA application generally need FDA approval before they can be modified. Similarly, some modifications made to products cleared through a 510 (k) may require a new 510 (k). Either process can be expensive, lengthy and unpredictable. ~~The~~ **20The** FDA may not approve or clear our 510 (k), de novo, or PMA applications on a timely basis or at all. Such delays or refusals could have a material adverse effect on our business operations and financial condition. The FDA may also change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other action which may prevent or delay approval or clearance of our products under development. Any of these actions could have a material adverse effect on our business operations and financial condition. The FDA and the U. S. Federal Trade Commission (" FTC ") also regulate the advertising and promotion of our devices to ensure that the claims we make are consistent with our regulatory clearances or approvals, that there are adequate and reasonable data to substantiate the claims and that our promotional labeling and advertising is neither false nor misleading in any respect. If the FDA or the FTC determines that any of our advertising or promotional claims are misleading, not substantiated or not permissible, we may be subject to enforcement actions, including FDA warning letters, and we may be required to revise our promotional claims and make other corrections or restitutions. FDA and state authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA or state agencies, which may include any of the following sanctions, among others: ● adverse publicity, warning letters, fines, injunctions, consent decrees, and civil penalties; ● obligations to repair, replace, refund, or recall our marketed devices, or government seizure of them; ● operating restrictions, partial suspension, or total shutdown of production; ● refusing our requests for 510 (k) clearance or premarket

approval of new devices, new intended uses or modifications to existing devices; ● withdrawing 510 (k) clearance or premarket approvals that have already been granted; and ● criminal prosecution. If any of these events were to occur, our business and financial condition would be harmed. ~~16The~~ -- **The** mechanism of action of NPS technology platform has not been fully determined or validated. The exact mechanism (s) of action (s) of our NPS technology platform is not fully understood, and data are still being gathered regarding its use. Furthermore, there are only a relatively small number of scientists and researchers who can be considered experts in the use of this emerging technology. Insofar as potential regulators, partners or investors value a clear understanding of a technology' s mechanism of action, this limitation could make it more challenging for us to obtain requisite regulatory approvals, investments or a partnership on favorable terms as a result. **21We** Our CellFX System and any future product..... planned product, if approved. We may find it difficult to enroll patients in our clinical trials. If we cannot enroll a sufficient number of eligible patients to participate in our clinical trials, we may not be able to initiate or continue them, which could delay or prevent development of our product candidates. Identifying and qualifying patients to participate in clinical trials of our product candidates is critical to our success. The timing of our clinical trials depends on the speed at which we can recruit patients to participate in testing our product candidates as well as completion of required follow- up periods. In general, if patients are unwilling to participate in our trials because of negative publicity from adverse events in the health care industry or for other reasons, including competitive clinical trials for similar patient populations, the timeline for recruiting patients, conducting trials and obtaining regulatory approval or clearance of planned products may be delayed. If there are delays in accumulating the required patients and patient data, there may be delays in completing the trial. Further, if any of our clinical trial sites fail to comply with required good clinical practices, we may be unable to use the data gathered at those sites. Also, if our clinical investigators fail to carry out their contractual duties or regulatory obligations or fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols or for other reasons, our clinical trials may be delayed, suspended, or terminated. These delays could result in increased costs, delays in advancing our product development, delays in testing the effectiveness of our technology or termination of the clinical trials altogether, and delays in obtaining regulatory authorization for our products. ~~17Laboratory~~ -- **Laboratory** conditions differ from commercial conditions and field conditions, and the safety and effectiveness of our product candidates may depend on the technique of the user. Observations and developments that may be achievable under laboratory circumstances may not be able to be replicated in broader research and development phases, in commercial settings, or in the use of any of any product or product candidates in the field. Furthermore, our NPS technologies will be administered by healthcare professionals and will require a degree of training and practice to administer correctly. Treatment results achieved in the laboratory or in clinical trials conducted by us or by other investigators may not be representative of the results actually encountered during commercial use of our products due to variability in administration technique. The training and skills of investigators in our clinical trials may not be representative of the training and skills of future product users, which could negatively affect treatment results and the reputation of the Company or its products. In addition, there may be a selection bias in the patients and / or sites of administration chosen for any clinical trials that would positively affect treatment results that may not be representative or predictive of real- world experience with our products, including the CellFX System. Issues with our firmware and software may negatively affect the function of our devices. The safety and effectiveness of CellFX procedures and therapies may depend, in part, on the function of firmware run by the microprocessors embedded in the device and associated software. This firmware and software is proprietary to us. While we have made efforts to test the firmware and software extensively, both are potentially subject to malfunction which in turn may harm patients. Further, our proprietary firmware and software may be vulnerable to physical break- ins, hackers, improper employee or contractor access, computer viruses, programming errors, data breaches, or similar problems. Any of these might result in harm to patients or the unauthorized release of confidential medical, business or other information belonging to us or to other persons. We may encounter manufacturing problems or delays..... frequently influenced by Medicare coverage determinations. Risks Related to Intellectual Property **, Cybersecurity, Data Privacy, & Litigation** If we are unable to protect our intellectual property, then our financial condition, results of operations and the value of our technology and products could be adversely affected. Patents and other proprietary rights are essential to our business and our ability to compete effectively with other companies is dependent upon the proprietary nature of our technologies. Similarly, our future success partnering our NPS technologies, including our CellFX System, will depend greatly on the perceived strength and reach of the patents protecting those technologies against unlicensed competitors. We also rely upon trade secrets, know- how, continuing technological innovations, and licensing opportunities to develop, maintain and strengthen our competitive position. We seek to protect these, in part, through confidentiality agreements with certain employees, consultants and other parties. Our success will depend in part on the ability of our licensors and us to obtain, to maintain (including making periodic filings and payments) and to enforce patent protection for the licensed intellectual property, in particular, those patents to which we have secured rights. We may not successfully prosecute or continue to prosecute the patent applications which we have licensed. Even if patents are issued in respect of these patent applications, we may fail to maintain these patents or may determine not to pursue litigation against entities that are infringing upon these patents. Without adequate protection for the intellectual property that we own or license, other companies might be able to offer substantially identical products for sale, which could unfavorably affect our competitive business position and harm our business prospects. Even if issued, patents may be challenged, invalidated, or circumvented, which could limit our ability to stop competitors from marketing similar products or limit the length of term of patent protection that we may have for our products. Litigation or third- party claims of intellectual property infringement or challenges to the validity of our patents would require us to use resources to protect our technology and may prevent or delay our development, regulatory approval or commercialization of our product candidates. If we are the target of claims by any third party asserting that our products or intellectual property infringe upon the rights of others, we may be forced to incur substantial expenses or divert substantial employee resources from our business. If successful, such claims could result in our having to pay substantial damages or could prevent us from developing one or more products or product candidates.

Further, if a patent infringement suit were brought against us or our collaborators, we or they could be forced to stop or delay research, development, manufacturing, or sales of the product or product candidate that is the subject of the suit. If we, or our collaborators, experience patent infringement claims, or if we elect to avoid potential claims others may be able to assert, we or our collaborators may choose to seek, or be required to seek, a license from the third party and would most likely be required to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if we or our collaborators were able to obtain a license, the rights may be nonexclusive, which would give our competitors access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations if, as a result of actual or threatened patent infringement claims, we or our collaborators are unable to enter into licenses on acceptable terms. This could harm our business significantly. The cost to us of any litigation or other proceeding, regardless of its merit, even if resolved in our favor, could be substantial. Some of our competitors may be able to bear the costs of such litigation or proceedings more effectively than we can because of their having greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Intellectual property litigation and other proceedings may, regardless of their merit, also absorb significant management time and employee resources. ~~19Our~~ **22Our** intellectual property rights will not necessarily provide us with competitive advantages. The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us or our future commercial partners to maintain a competitive advantage. The following examples are illustrative: ● others may be able to make products that are similar to our product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed; ● others may independently develop similar or alternative technologies without infringing on our intellectual property rights; ● issued patents that we own or have exclusively licensed may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors; ● we may obtain patents for certain products many years before we obtain marketing approval for products utilizing such patents, and because patents have a limited life, which may begin to run prior to the commercial sale of the related product, the commercial value of our patents may be limited; ● our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets; ● we may fail to develop additional proprietary technologies that are patentable; ● the laws of certain foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States, or we may fail to apply for or obtain adequate intellectual property protection in all the jurisdictions in which we operate; and ● the patents of others may have an adverse effect on our business, for example by preventing us from marketing one or more of our product candidates for one or more indications. Any of the aforementioned threats to our competitive advantage could harm our business. If we are unable to protect the confidentiality of our proprietary information and know- how, the value of our technology and products could be adversely affected. In addition to patented technology, we rely upon, among other things, unpatented proprietary technology, processes, trade secrets, and know- how. Any involuntary disclosure to, or misappropriation by, third parties of our confidential or proprietary information could enable competitors to duplicate or surpass our technological achievements, potentially eroding our competitive position in our market. We seek to protect confidential and proprietary information in part by confidentiality agreements with our employees, consultants and third parties. While we require, as a matter of company policy, that all of our employees, consultants, advisors, and any third parties who have access to our proprietary know- how, information or technology to enter into confidentiality agreements, we cannot be certain that this know- how, information and technology will not be improperly disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. These confidentiality agreements may be terminated or breached, and we may not have adequate remedies for any such termination or breach. Furthermore, these agreements may not provide meaningful protection for our trade secrets and know- how in the event of unauthorized use or disclosure. If we are unable to protect the intellectual property used in our products, others may be able to copy our innovations which may impair our ability to compete effectively in our markets. Evaluating the strength and enforceability of our patents involves complex legal and scientific questions and can be uncertain. Both our patents and patent applications can be challenged by third parties and our patent applications may fail to result in issued patents. Moreover, both our existing and future patents may be too narrow to prevent third parties from developing or designing around our intellectual property and, in that event, we may lose competitive advantage and our business may suffer. We may not be able to protect our intellectual property rights throughout the world. Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our current or future product candidates, if any, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. **will likely result in additional costs** ~~insurance may not be sufficient to cover the financial~~ , ~~legal~~ **and may require us to change how we manufacture our products** , **which could have a material adverse effect on our** business ~~or reputational losses that may result from an interruption or breach of our systems~~ .Product liability lawsuits against us could cause us to incur substantial liabilities and limit commercialization of our product or any future products that we may develop.We face an inherent risk of product liability exposure related to the sale of our product and the future sale of planned products and the use of these in human clinical studies.For example,we may be sued

if our product or any of our product candidates,including any that are developed in combination therapies,allegedly causes injury,or is found to be otherwise unsuitable during product testing,manufacturing,marketing,or sale.Any such product liability claims may include allegations of defects in manufacturing,defects in design,a failure to warn of dangers inherent in the product,negligence,strict liability,or a breach of warranties.We may also be subject to liability for a misunderstanding of,or inappropriate reliance upon,the information we provide.If we cannot successfully defend ourselves against claims that our product or planned products caused injuries,we may incur substantial liabilities.Regardless of merit or eventual outcome,liability claims may result in,among other things:● decreased demand for our product or any planned products that we may develop;● injury to our reputation and significant negative media attention;● withdrawal of patients from our clinical studies or cancellation of studies;● significant costs to defend the related litigation and distraction to our management team;● substantial monetary awards to patients;● loss of revenue;● government investigations or enforcement actions;and ● the inability to commercialize any future products that we may develop.For example,during the course of treatment,patients may suffer adverse events for reasons that may or may not be related ~~to the 20Risks~~ **24Risks** Related to Government Regulation We are subject to stringent domestic and foreign regulation. Any unfavorable regulatory action or adverse change in law may materially and adversely affect our future financial condition and business operations and prospects. The CellFX System and any other potential devices and products we develop are, and will continue to be, subject to extensive, rigorous, and ongoing regulation by numerous government agencies, including the FDA and similar foreign regulatory authorities. To varying degrees, each of these agencies monitors and enforces our compliance with laws and regulations governing the development, testing, manufacturing, labeling, marketing, distribution, and the safety and effectiveness of our medical technology. The process of obtaining and maintaining marketing approval or clearance from the FDA and similar foreign regulatory authorities for new devices and products, or for enhancements, expansion of the indications or modifications to existing products, could: ● take a significant indeterminate amount of time; ● require the expenditure of substantial resources; ● involve rigorous preclinical and clinical testing, and possibly post- market surveillance; ● involve modifications, repairs or replacements of our products; ● require design changes of our products; ● result in limitations on the indicated uses of our products; and ● result in our never being granted the regulatory approval or clearance we seek. If we experience any of these occurrences, our operations may suffer and we might experience harm to our competitive standing, which could adversely affect our financial condition. We are subject to, and will have ongoing responsibilities under, FDA and international regulations, both before and after a product is approved or cleared and commercially released. Compliance with applicable regulatory requirements is subject to continual review and is monitored rigorously through periodic inspections. If an inspection were to conclude that we are not in compliance with applicable laws or regulations, or that any of our devices are ineffective or pose an unreasonable health risk, the FDA or similar foreign regulatory authorities could ban such devices or products, detain or seize such devices or products, order a recall, repair, replacement, or refund of such devices or products, or require us to notify health professionals and others that the therapies, devices or products present unreasonable risks of substantial harm to the public health. Additionally, the FDA or similar foreign regulatory authorities may impose other operating restrictions, enjoin and restrain certain violations of applicable law pertaining to our devices and products or assess civil or criminal penalties against our officers, employees, or us. The FDA and similar foreign regulatory authorities have been increasing their scrutiny of the industry and governments are expected to continue to scrutinize the industry closely with inspections and possibly enforcement actions. Any adverse regulatory action, depending on its magnitude, may restrict us from effectively manufacturing, marketing and selling our devices and products, including the CellFX System. In addition, negative publicity and product liability claims resulting from any adverse regulatory action could have a material adverse effect on our financial condition and results of operations. **U. S. Healthcare Reform Changes in healthcare policy could increase our costs and subject us to additional regulatory requirements that may interrupt commercialization of our current and future solutions. Changes in healthcare policy could increase our costs, decrease our revenues, and impact sales of and reimbursement for our current and future solutions. The Affordable Care Act substantially changes the way healthcare is financed by both governmental and private insurers, and significantly impacts our industry. The Affordance Care Act contains a number of provisions that impact our business and operations, some of which in ways we cannot currently predict, including those governing enrollments in federal healthcare programs and reimbursement changes. There will continue to be proposals by legislators at both the federal and state levels, regulators, and third- party payors to reduce costs while expanding individual healthcare benefits. Certain of these changes could impose additional limitations on the prices we will be able to charge for our current and future solutions or the amounts of reimbursement available for our current and future solutions from governmental agencies or third- party payors. While in general it is too early to predict specifically what effect the Affordable Care Act and its implementation or any future healthcare reform legislation or policies will have on our business, current and future healthcare reform legislation and policies could have a material adverse effect on our business and financial condition.** ~~All~~ **25All** our product development depends upon maintaining strong working relationships with physicians. The development, marketing, and sale of any future products in development, depends upon our ability to maintain strong working relationships with physicians. We rely on these professionals to provide us with considerable knowledge and experience regarding the development, marketing, and sale of our products. Physicians assist us in clinical trials and as researchers, marketing and product consultants and public speakers. If we cannot maintain our strong working relationships with these professionals and continue to receive their advice and input, the development and marketing of our products could suffer, which could harm our business, financial condition and results of operations. The medical device industry' s relationship with physicians is under increasing scrutiny by the Office of Inspector General (" OIG "), the Department of Justice (" DOJ "), state attorneys general, and other foreign and domestic government agencies. Our failure to comply with laws, rules and regulations governing our relationships with physicians, or an investigation into our compliance by the OIG, DOJ, state attorneys general, and other government agencies, could significantly harm our business, including compromising the use or integrity of our

clinical data in regulatory submissions to the FDA or similar regulatory authorities. We are subject to healthcare and other laws and regulations relating to our business and could face substantial penalties if we are determined not to have fully complied with such laws, which could have an adverse impact on our business. We are exposed to the risk that our employees and independent contractors, including principal investigators, consultants, any commercial collaborators, service providers and other vendors may engage in misconduct or other illegal activity. Misconduct by these parties could include intentional, reckless and / or negligent conduct or other unauthorized activities that violate applicable laws or regulations. There are many federal and state laws and regulations prohibiting fraud and abuse in the healthcare industry that can result in significant criminal and civil penalties. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell, and distribute our products for which we obtain marketing approval or clearance. We **are exposed to the risk that our employees and independent contractors, including principal investigators, consultants, any commercial collaborators, service providers and other vendors may engage in misconduct or other illegal activity. Misconduct by these parties could include intentional, reckless and / or negligent conduct or other unauthorized activities that violate applicable laws or regulations. There are many federal and state laws and regulations prohibiting fraud and abuse in the healthcare industry that can result in significant criminal and civil penalties. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell, and distribute our products for which we obtain marketing approval or clearance. Such laws include: ● U. S. 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 or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program, such as Medicare and Medicaid. The term " remuneration " has been broadly interpreted to include anything of value, and the government can find a violation of the Anti- Kickback Statute without proving that a person or entity had actual knowledge of the law or a specific intent to violate it. In addition, the government may assert that a claim including items or services resulting from a violation of the U. S. federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act; ● U. S. federal civil and criminal false claims laws and civil monetary penalties laws, including the civil False Claims Act, which, among other things, impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the U. S. government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U. S. government; ● HIPAA imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation; ● HIPAA, as amended by HITECH, and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization by covered entities subject to the rule, such as health plans, healthcare clearinghouses and healthcare providers as well as their business associates that perform certain services for or on their behalf involving the use or disclosure of individually identifiable health information; ● the U. S. Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children' s Health Insurance Program (with certain exceptions) to report annually to the government information related to payments or other " transfers of value " made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually to the government ownership and investment interests held by these physicians and their immediate family members; ● the CCPA requires covered companies to, among other things provide new disclosures to California consumers and afford such consumers new abilities to opt- out of certain sales of personal information. We cannot yet predict the impact of the CCPA or the recently approved CPRA on our business or operations, but it may require us to modify our data processing practices and policies and could cause us to incur substantial costs and expenses in an effort to comply; ● federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and ● analogous state and non- U. S. laws and regulations, such as state anti- kickback and false claims laws, which may apply to our business practices, including, but not limited to, research, distribution, sales, and marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third- party payors, including private insurers; state laws that require device companies to comply with the industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the U. S. government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information; and state and non- U. S. laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. We** have implemented compliance related programs and procedures consistent with our stage of development to help identify and deter healthcare and other violations by employees and other third parties that perform services for us. Notwithstanding our efforts, however, it is possible that governmental authorities may conclude that our business practices do not comply with

current or future statutes, regulations, agency guidance, or case law involving applicable healthcare or other applicable laws. Also, any material change to any of the laws or regulations applicable to our business could harm our business, financial condition and results of operations **. ~~21To~~ 26To** obtain the necessary device approvals or clearances from regulatory authorities for our future product candidates, we will have to conduct various preclinical and clinical tests, which may be costly and time consuming, and may not provide results that will allow us to seek regulatory approval or clearance. The number of preclinical and clinical tests that will be required for regulatory clearance or approval varies depending on the disease or condition to be treated, the method of treatment, the nature of the device, the jurisdiction in which we are seeking approval or clearance and the applicable regulations. Regulatory agencies, including those in the United States, Canada, Europe, and other jurisdictions where medical devices and products are regulated can delay, limit or deny approval of a product for many reasons. For example, regulatory agencies: ● may not deem a technology or device to be reasonably safe or effective for any intended use or indication; ● may interpret data from preclinical and clinical testing differently than we do; ● may determine our manufacturing facility or processes do not comply with quality system regulations; ● may conclude that our products do not meet quality standards for durability, long- term reliability, biocompatibility, electromagnetic compatibility, or electrical safety; or ● may change their approval or clearance policies or adopt new regulations in a manner that is adverse to us. These regulators may make requests or disagree with us regarding the design or conduct of our clinical trials, resulting in an increased risk of difficulties or delays in obtaining regulatory approval or clearance on future product candidates, or expanded indications of use for our existing products, and increased costs. Even if a potential device or product ultimately is cleared or approved by regulatory authorities, it may be cleared or approved only for narrow indications which may render it commercially less viable. Even if we complete clinical testing and a potential device or product of ours is cleared or approved, it may not be cleared or approved for the indications that are necessary or desirable for a successful commercialization. Regulators may grant marketing authorization contingent on the performance of costly additional clinical trials which may be required after approval or clearance. Regulators also may approve or clear our lead product candidates, including the CellFX System, for a more limited indication or a narrower patient population than we originally requested. Our preference will be to obtain as broad an indication as possible for use in connection with the particular disease or treatment for which it is designed. However, the final indication or labeling may be more limited than we originally seek. Any limitation on use may make the device or product commercially less viable and more difficult, if not impractical, to market. Therefore, we may not obtain the revenues that we seek in respect of the proposed product, and we will not be able to become profitable and provide an investment return to our investors. We will be subject to ongoing requirements and inspections that could lead to the restriction, suspension or revocation of our clearance. We, as well as any potential third- party manufacturer, will be required to adhere to FDA quality systems requirements, which include testing, control, and documentation requirements. We will be subject to similar regulations in foreign countries. Even when regulatory approval or clearance of a product is granted, the approval or clearance may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval or clearance, or contain requirements for costly post- marketing testing and surveillance to monitor the safety or efficacy of the product. Ongoing compliance with quality system regulations and other applicable regulatory requirements is strictly enforced in the United States through periodic inspections by state and federal agencies, including the FDA, and in international jurisdictions by comparable agencies. Failure to comply with regulatory requirements could result in, among other things, warning letters, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, failure to obtain premarket clearance or premarket approval for devices, withdrawal of approvals or clearances previously obtained, and criminal prosecution. The restriction, suspension or revocation of regulatory approvals or clearances, or any other failure to comply with regulatory requirements would limit our ability to operate and could materially increase our costs. Our employees, collaborators and other personnel may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading. We are exposed to the risk of fraud or other misconduct by our employees, collaborators and other personnel, which could include intentional, reckless and / or negligent conduct or disclosure that violates: (i) the laws of the FDA and other similar foreign regulatory bodies, including those laws requiring the reporting of true, complete and accurate information to such regulators; (ii) manufacturing standards; or (iii) healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws. These laws may impact, among other things, future sales, marketing and education programs. The promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud and abuse, kickbacks, self- dealing, and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commissions, certain customer incentive programs, and other business arrangements generally. Activities subject to these laws also involve the use of information obtained in the course of patient recruitment for clinical trials. We adopted a code of conduct applicable to all of our employees, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent unlawful activities may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions. Whether or not we are successful in defending against any such actions or investigations, we could incur substantial costs, including legal fees, and divert the attention of management in defending ourselves against any of these claims or investigations, which could have a material adverse effect on our business and financial condition. ~~22Healthcare policy changes~~ **We are subject to environmental regulations and any failure to comply with applicable laws could subject us to significant liabilities and harm our business. We are subject to a variety of local** , ~~including recent~~ **state,** federal ~~legislation~~ **, and foreign government regulations relating** to ~~reform~~ **the storage, discharge, handling, emission, generation, manufacture, and disposal of toxic or other hazardous substances used in the manufacture of our products. The failure**

to comply with past, present or future laws could result in the imposition of fines, third- party property damage and personal injury claims, investigation and remediation costs, the suspension of production, or a cessation of operations. We also expect that our operations will be affected by other new environmental and health and safety laws on an ongoing basis. Although we cannot predict the ultimate impact of any such new laws, ~~the~~ **they** ~~U. S. healthcare system~~ **will likely result in additional costs** , **and** may **require us to change how we manufacture our products, which could** have a material adverse effect on **our business. 27We could be negatively impacted by actual or perceived violations of applicable anti- corruption law or our own internal policies designed to ensure ethical business practices. We are subject to anti- bribery, anti- corruption, and anti- money laundering laws, including the U. S. Foreign Corrupt Practices Act of 1977, or FCPA, and similar anti- bribery laws in non- U. S. jurisdictions, as well as export control laws, customs laws, sanctions laws and other laws governing our operations. 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. Anti- corruption laws, such as the FCPA and the U. K. Anti- Bribery Act, generally prohibit** us ~~. Proposals by~~ **and our employees and intermediaries from bribing, being bribed or making** ~~the~~ **other** ~~federal~~ **prohibited payments to** government **officials or other persons to obtain or retain business or gain some other business advantage. The FCPA also imposes accounting standards and requirements on publicly traded U. S. corporations and their foreign affiliates** , ~~state governments~~ **which are intended to prevent the diversion of corporate funds to the payment of bribes and other improper payments. Numerous other laws restrict** , **and in some cases prohibit, U. S. companies from directly or indirectly selling goods, technology or services to people or entities in certain countries. In addition, these laws require that we exercise care in structuring our sales and marketing practices and effecting product registrations in foreign countries. Compliance with these** ~~regulators~~ **regulations** ~~,~~ **is costly. We participate in collaborations** and **relationships with** third **parties whose actions could potentially subject us to liability under these anti** - ~~party payors~~ **corruption laws. In addition, we cannot predict the nature, scope, or effect of future regulatory requirements** to ~~control~~ **which** ~~or~~ **our** ~~manage~~ **international operations might be subject or the manner in which existing laws might be administered or interpreted. Although we have implemented company policies requiring our employees and consultants to comply with the FCPA and similar laws, such policies may not be effective at preventing all potential FCPA or** ~~the~~ **other** ~~increased costs~~ **violations. There can be No assurance that none** of ~~healthcare~~ **our employees** and ~~to reform~~ **agents, or** ~~the~~ **those** ~~U. S. healthcare system may impact~~ **companies to which we outsource certain portions of** our business ~~significantly~~ **operations, will not take actions that violate our policies or applicable laws, for which we may be ultimately held responsible** . ~~Certain proposals could limit the prices~~ **Our development of infrastructure designed to identify anti- corruption matters and monitor compliance is at an early stage. If** we are **not in compliance with** ~~able to charge for our products or the~~ **these** ~~coverage~~ **laws, we may be subject to criminal** and **civil penalties, disgorgement** ~~reimbursement available for our products~~ and ~~could limit the~~ **other** ~~acceptance~~ **sanctions** and **remedial measures, and legal expenses, which** ~~availability of our products. The adoption of proposals to control costs~~ could have **an** ~~a material~~ adverse ~~effect~~ **impact** on our business ~~and~~ **,** financial condition **, results of operations, and liquidity** . ~~We cannot predict~~ **Likewise, any investigation of any potential violations of** ~~the~~ **these laws by respective government bodies could also have an adverse** ~~initiatives that may be adopted in the future or their full~~ impact on our **reputation, our** business ~~. The continuing efforts of governments~~ , **results** ~~insurance companies, managed care organizations, and other payors~~ of ~~healthcare services to~~ **operations, and financial** ~~contain~~ - **condition** ~~or reduce costs of healthcare may negatively impact our ability to set a price that we believe is fair for our products, our ability to generate revenue and achieve profitability, and the availability of capital~~ . Risks Related to Owning Our Common Stock The price of our common stock has been, and we expect it to continue to be, highly volatile, and you may be unable to sell your shares at or above the price you paid to acquire them. The market price of our common stock has been highly volatile, and we expect it to continue to be highly volatile for the foreseeable future in response to many risk factors listed in this section, and others beyond our control, including: ● results of clinical trials of our planned products or those of our competitors; ● actions by regulatory bodies, such as the FDA, that affect our business or have the effect of delaying or rejecting approval or clearance of our planned products; ● actual or anticipated fluctuations in our financial condition and operating results; ● announcements by our customers, partners or suppliers relating directly or indirectly to our products, services or technologies; ● announcements of technological innovations by us or our competitors; ● changes in laws or regulations applicable to the CellFX System or to our planned ~~products~~ **end- effectors** ; ● announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, capital commitments, or achievement of significant milestones; ● additions or departures of key personnel; ● competition from existing products or new products that may emerge; ● fluctuations in the valuation of companies perceived by investors to be comparable to us; ● disputes or other developments related to proprietary rights, including patents, litigation matters or our ability to obtain intellectual property protection for our technologies; ● actual or alleged security breaches; ● announcements or expectations of additional financing efforts; ● sales of our common stock by us or our stockholders; ● stock price and volume fluctuations attributable to inconsistent trading volume levels of our shares; ● reports, guidance and ratings issued by securities or industry analysts; ● overall conditions in our industry and market **,** including the negative impact of ~~COVID- 19~~ **armed conflicts, health epidemics and climate change** on the global economy and markets; and ● general economic and market conditions. ~~23Any~~ **28Any** of the above may cause our stock price or trading volume to decline. Stock markets in general, and the market for companies in our industry in particular, have experienced price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many companies, including ours. These fluctuations often have been unrelated or disproportionate to the operating performance of those companies. These broad market and industry fluctuations, as well as general economic, political and market conditions such as recessions, interest rate changes or international currency fluctuations, may negatively impact the market price of our common stock. Investors may not realize any return on their investment in us and may lose some or all of their investment. In the past, companies that have experienced

volatility in the market price of their stock have been subject to securities class action litigation. The high volatility of our stock price, the composition of our Board and governance practices, including our Executive Chairman' s repeated interest in acquiring additional shares in our Company through related party transactions, as well as countless other factors not identified above, increase the risk of securities litigation or shareholder derivative litigation against the Company and its Directors. Securities litigation against us could result in substantial costs and divert our management' s attention from other business concerns and adversely impact our ability to raise capital to fund our operations, which could seriously harm our business. Sales or purchases of shares of our common stock may adversely affect the market for our common stock. If we or our stockholders, particularly our directors, executive officers and significant stockholders, sell or purchase, register for sale, or indicate an intent to sell or purchase, shares of our common stock in the public market, it may have a material adverse effect on the market price of our common stock. In particular, Robert W. Duggan, our majority stockholder and Executive Chairman, is not subject to any contractual restrictions with us on his ability to sell or transfer the shares of our common stock that he holds, and these sales or transfers could create substantial declines in the price of our securities or, if these sales or transfers were made to a single buyer or group of buyers, could contribute to a transfer of control of our Company to a third party. Many of Mr. Duggan' s shares in the Company have been registered for resale pursuant to an effective registration statement on Form S- 3. Sales by Mr. Duggan of a substantial number of shares, or the expectation of such sales, could cause a significant reduction in the market price of our common stock ~~. Additionally, we maintain a shelf registration statement on Form S- 3 pursuant to which we may, from time to time, sell up to an aggregate of $ 160 million of our common stock, preferred stock, depositary shares, warrants, debt securities, or units. We may also issue shares of common stock or securities convertible into, exchangeable or exercisable for our common stock from time to time in connection with financings, acquisitions, investments, or otherwise. Any such issuances would result in dilution to some or all of our existing stockholders and could cause our stock price to fall. We may also sell shares or other securities at a price per share that is less than the price per share paid by existing investors, and investors purchasing shares or other securities in the future could have rights superior to existing stockholders~~ . We do not know whether an active, liquid and orderly trading market will exist for our common stock and as a result it may be difficult for you to sell your common stock. Prior to our initial public offering in May 2016, there was no public market for our common stock. Although our common stock is listed on The Nasdaq Capital Market (" Nasdaq "), the market for our shares has demonstrated varying levels of trading activity. As a result of these and other factors, you may not be able to sell your common stock quickly, at or above the price paid to acquire the stock or at all. Further, an inactive market may also harm our ability to raise capital by selling additional common stock and may harm our ability to enter into strategic collaborations or acquire companies or products by using our common stock as consideration. Concentration of ownership by our principal stockholder limits the ability of others to influence the outcome of director elections and other transactions requiring stockholder approval, or create the potential for conflicts of interest. A majority percentage of our outstanding stock is held by Robert W. Duggan, Executive Chairman of our Board, who beneficially owns approximately ~~56~~ **69** % of our common stock outstanding as of the date of this Annual Report. As a result, Mr. Duggan has control over corporate actions requiring stockholder approval, including the following actions: ● to elect or defeat the election of our directors; ● to amend or prevent amendment of our certificate of incorporation or bylaws; ● to effect or prevent a merger, sale of assets or other corporate transaction; and ● to control the outcome of any other matter submitted to our stockholders for vote. ~~24Mr~~ **29Mr** . Duggan' s controlling interest in the Company also creates the potential for conflicts of interest which be viewed unfavorably by minority stockholders, thereby hurting our stock price. For example, in November 2021, we engaged outside legal counsel to represent the Company even though the same legal counsel currently represents Mr. Duggan personally in other matters. This legal counsel represented Mr. Duggan in certain related party transactions described herein and could represent both the Company and Mr. Duggan in future related party transactions. ~~Three~~ **Four** of our directors, including Mr. Duggan **and Manmeet Soni, our Lead Independent Director and Audit Committee Chairman** , are executives at Summit Therapeutics Inc., another company in which Mr. Duggan holds a controlling equity interest. There are no family relationships among any of our directors or executive officers, however, Mr. Duggan and Dr. Zanganeh have a personal relationship with each other. Additionally, because Mr. Duggan owns a majority of our outstanding shares, we are considered to be a " controlled " company under applicable Nasdaq rules. As such, we may voluntarily elect not to comply with certain of Nasdaq' s corporate governance requirements, such as certain rules concerning the setting of executive compensation and the appointment of directors. Accordingly, during the period we remain a controlled company and during any transition period following a time when we are no longer a controlled company, other stockholders may not have the same protections afforded to stockholders of companies that are subject to all of the corporate governance requirements of the Nasdaq Stock Market. As a member of our Board, Mr. Duggan will adhere to the corporate governance standards adopted by the Company. Even though we have not yet elected to take advantage of any of these corporate governance exemptions permitted by Nasdaq, Mr. Duggan' s stock ownership and our status as a " controlled " company may discourage a potential acquirer from making a tender offer or otherwise attempting to obtain control of our Company, which in turn could reduce our stock price or prevent our stockholders from realizing a premium over our stock price. In addition, Mr. Duggan is not subject to any contractual restrictions on his ability to acquire additional shares of common stock and any such purchases, including purchases of equity securities in connection with any rights offerings or any alternative equity or equity- linked offering that we may conduct, could result in his acquisition of a larger percentage of our common stock. Management currently beneficially holds a small percentage of our common stock. Other than their positions as directors or officers, and the restriction on the stockholders being able to call a special meeting limited to holders of 15 % or more of the outstanding shares of common stock, our management will not be able to greatly influence corporate actions requiring stockholder approval. Robert W. Duggan' s controlling ownership position may impact our stock price and may deter or prevent efforts by others to acquire us, which could prevent our stockholders from realizing a control premium. Robert W. Duggan is our Executive Chairman, and he beneficially owns approximately ~~56~~ **69** % of our common stock outstanding as of the date of this Annual Report. In addition, Mr. Duggan is not subject to any contractual

restrictions on his ability to acquire additional shares of common stock, and any such purchases, including purchases of equity securities in connection with any rights offerings or any alternative equity or equity- linked offering that we may conduct, could result in his acquisition of a majority of our common stock. As a result of Mr. Duggan' s controlling ownership and position as Executive Chairman, others may be less inclined to pursue an acquisition of us and therefore we may not have the opportunity to be acquired in a transaction that stockholders might otherwise deem favorable, including transactions in which our stockholders might realize a substantial premium for their shares. In addition, public speculation regarding Mr. Duggan, as well as our relationship with Mr. Duggan, could cause our stock price to fluctuate. We have incurred and will continue to incur costs as a result of operating as a public company and our management has been and will be required to devote substantial time to public company compliance initiatives. As a public company, listed in the United States, we have incurred and will continue to incur significant legal, accounting and other expenses due to our compliance with regulations and disclosure obligations applicable to us, including compliance with the Sarbanes- Oxley Act of 2002, or the Sarbanes- Oxley Act, as well as rules implemented by the SEC and Nasdaq. The SEC and other regulators have continued to adopt new rules and regulations and make additional changes to existing regulations that require our compliance. Stockholder activism, the current political environment, and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact, in ways we cannot currently anticipate, the manner in which we operate our business. Our management and other personnel have and will continue to devote a substantial amount of time to these compliance programs and monitoring of public company reporting obligations and, as a result of the new corporate governance and executive compensation related rules, regulations, and guidelines prompted by the Dodd- Frank Wall Street Reform and Protection Act, or the Dodd- Frank Act, and further regulations and disclosure obligations expected in the future, we will likely need to devote additional time and costs to comply with such compliance programs and rules. New laws and regulations as well as changes to existing laws and regulations affecting public companies, including the provisions of the Sarbanes- Oxley Act, the Dodd- Frank Act, and rules adopted by the SEC and Nasdaq, will likely result in increased costs to us as we respond to their requirements. We are currently evaluating and monitoring developments with respect to these rules and regulations, and we cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. ~~25Furthermore~~ **30Furthermore** , these and future rules and regulations could make it more difficult or more costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage ~~. For example, we determined not to renew our director and officer liability insurance this year due to disproportionately high premiums quoted by insurance companies. Instead, we and Robert W. Duggan, Executive Chairman of our board of directors, have entered into a letter agreement pursuant to which Mr. Duggan has agreed with us to personally provide " Side A " indemnity coverage on substantially the same terms as our prior coverage program for a one- year period~~ . The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as our executive officers. We are a " smaller reporting company "; we cannot be certain if the applicable reduced disclosure requirements will make our common stock less attractive to investors. **We** ~~Through the end of 2021, we were an " emerging growth company, " as defined in the JOBS Act, and we took advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not " emerging growth companies " including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. While we are no longer an emerging growth company, we still~~ qualify as a " smaller reporting company, " as defined in the Exchange Act, and so long as we remain a smaller reporting company, we benefit from and may take advantage of scaled disclosure requirements. We cannot know if investors find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile and it may be difficult for us to raise additional capital as and when we need it. Investors may be unable to compare our business with other companies in our industry if they believe that our reporting is not as transparent as other companies in our industry. If we are unable to raise additional capital as and when we need it, our financial condition and results of operations may be materially and adversely affected. If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our market price and trading volume could decline. The trading market for our common stock will depend on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. We currently have only limited analyst coverage of us and there can be no assurance that analysts will continue to cover us or provide favorable coverage. If one or more of the analysts who cover us downgrade our stock or change their opinion of our stock, our market price would likely decline. If analysts cease coverage of our Company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline. We have not paid dividends in the past and have no plans to pay dividends. For the foreseeable future, we plan to reinvest all of our earnings, to the extent we have earnings, into our product research and development efforts, so we have no plans to pay any cash dividends with respect to our securities. We cannot assure you that we would, at any time, generate sufficient surplus cash that would be available for distribution to the holders of our common stock as a dividend. Therefore, you should not expect to receive cash dividends on our outstanding common stock. 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 and limit the market price of our common stock. Certain anti- takeover provisions of Delaware law and provisions in our certificate of incorporation and bylaws may have the effect of delaying or preventing a change of control or changes in our management. These provisions could also

make it difficult for stockholders to elect directors that are not nominated by the current members of our board of directors or take other corporate actions, including effecting changes in our management. Our certificate of incorporation and bylaws include provisions that: ● authorize our board of directors to issue, without further action by the stockholders, up to 50, 000, 000 shares of preferred stock and up to approximately 500, 000, 000 shares of authorized but unissued shares of common stock; ● require that any action to be taken by our stockholders be effected at a duly called annual or special meeting and not by written consent; ~~26~~ **31** ● specify that special meetings of our stockholders can be called only by our board of directors, the chairman of our board of directors, any of our officers, or any stockholder holding at least fifteen percent (15 %) of the voting power of the capital stock issued and outstanding and entitled to vote; ● establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors; ● require the affirmative vote of holders of at least 66 2 / 3 % of the voting power of all the then outstanding shares of our voting stock, voting together as a single class, to amend provisions of our certificate of incorporation or our bylaws; ● give our board of directors the ability to amend our bylaws by majority vote; and ● provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum. 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, which is responsible for appointing the members of our management. Furthermore, our bylaws provide that unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall, to the fullest extent permitted by law, be the sole and exclusive forum for (a) any derivative action or proceeding brought on behalf of us, (b) any action asserting a claim of breach of fiduciary duty owed by any director, officer or other employee of us to us or our stockholders, (c) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our certificate of incorporation or our bylaws, or (d) any action asserting a claim governed by the internal affairs doctrine, in each case subject to the Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein; provided that, if and only if the Court of Chancery dismisses any such action for lack of subject matter jurisdiction, such action may be brought in another state or federal court sitting in Delaware. Our bylaws further provide that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. Any person or entity purchasing or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to these provisions. These exclusive- forum provisions may discourage lawsuits against us or our directors, officers, and employees. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which limits the ability of stockholders owning in excess of 15 % of our outstanding voting stock to engage in certain types of transactions with us. General Risk Factors Unfavorable global economic or political conditions could adversely affect our business, financial condition or results of operations. Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets, including the negative impact of ~~COVID- 19~~ **armed conflicts, health epidemics and global warming** on the global economy and markets. A global financial crisis or a banking crisis or a global or regional political disruption could cause extreme volatility in the capital and credit markets ~~, as has recently been the case due to COVID- 19~~ . The Company places its cash equivalents and investments with high credit quality financial institutions and, by policy, limits the amounts invested with any one financial institution or issuer and restricts the Company' s investments to U. S. treasuries and money market instruments. ~~The Company does not bank with Silicon Valley Bank, however~~ **However ,** in general the Company' s deposits held with banks ~~may~~ exceed the amount of insurance provided on such deposits. Despite our low **-** risk investment policies, a severe or prolonged economic downturn or political disruption could result in a variety of risks to our business, including our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy, banking crisis or political disruption could also strain our manufacturers or suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our products. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the political or economic climate and financial market conditions could adversely impact our business. If we experience material weaknesses in the future or otherwise fail to maintain an effective system of internal control over financial reporting in the future, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our common stock. As a public company, we are required to maintain internal control over financial reporting and to report any material weaknesses in such internal controls. Section 404 of the Sarbanes- Oxley Act requires that we evaluate and determine the effectiveness of our internal control over financial reporting and provide a management report on internal control over financial reporting. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis. Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time- consuming effort. Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with U. S. GAAP. We may not be able to complete our evaluation, testing and any required remediation in a timely fashion. During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal controls are effective. The identification of one or more material weaknesses would preclude a conclusion that we maintain effective internal control over financial reporting. Accordingly, there could continue to be a reasonable possibility that a material misstatement of our financial statements would not be prevented or detected on a timely basis. We are required to disclose changes made in our internal control and procedures on a quarterly basis. However, our independent registered public accounting firm will not be required to report on the effectiveness of our internal control over financial reporting pursuant to Section 404 of the Sarbanes- Oxley Act until we are no longer a " small reporting company. " At such time, our independent registered public accounting

firm may issue a report that is adverse in the event it is not satisfied with the level at which our controls are documented, designed or operating. Our remediation efforts may not enable us to avoid a material weakness in the future. If we are unable to assert that our internal control over financial reporting is effective, or when required in the future, if our independent registered public accounting firm is unable to express an unqualified opinion as to the effectiveness of our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could be adversely affected, and we could become subject to litigation risk and to investigations by Nasdaq, the stock exchange on which our securities are listed, by the SEC, and by other regulatory authorities, which could require additional financial and management resources. ~~27We~~ **32We** may become involved in litigation that may materially adversely affect us. From time to time, we may be involved in a variety of claims, lawsuits, investigations, or proceedings relating to securities laws, product liability, patent infringement, contract disputes, and other matters relating to various claims that arise in the normal course of our business in addition to governmental and other regulatory investigations and proceedings. In addition, third parties may, from time to time, assert claims against us. Such matters can be time- consuming, divert management' s attention and resources, cause us to incur significant expenses or liability and / or require us to change our business practices. Because of the potential risks, expenses and uncertainties of litigation, we may, from time to time, settle disputes, even where we have meritorious claims or defenses, by agreeing to settlement agreements. Because litigation is inherently unpredictable, we cannot assure you that the results of any of these actions will not have a material adverse effect on our business, financial condition, results of operations and prospects. See the section entitled " Legal Proceedings " for more detail on our current legal proceedings. Our facilities in California are located near known earthquake faults, and the occurrence of an earthquake or other catastrophic disaster could cause damage to our facilities and equipment, which could require us to cease or curtail operations. Our facilities in Hayward, California are located near known earthquake fault zones and are vulnerable to damage from earthquakes. We are also vulnerable to damage from other types of disasters, including fire, floods, power loss, communications failures, and similar events. If any disaster were to occur, our ability to operate our business at our facilities would be seriously, or potentially completely, impaired. In addition, the nature of our activities could make it difficult for us to recover from a natural disaster. The insurance we maintain may not be adequate to cover our losses resulting from disasters or other business interruptions. Accordingly, an earthquake or other disaster could materially and adversely harm our ability to conduct business.