Risk Factors Comparison 2023-03-30 to 2022-03-28 Form: 10-K

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

Careful consideration should be given to the following risk factors, in addition to the other information set forth in this Annual Report and in other documents that we file with the SEC, in evaluating the Company and our business. Investing in our common stock involves a high degree of risk. If any of the following risks and uncertainties actually occurs, our business, prospects, financial condition and results of operations could be materially and adversely affected. The risks described below are not intended to be exhaustive and are not the only risks that we face. New risk factors can emerge from time to time, and it is not possible to predict the impact that any factor or combination of factors may have on our business, prospects, financial condition and results of operations. Summary of Risk Factors • Risks Related to Our Business • We are a clinical- stage digital therapeutics company with a limited operating history and have incurred significant financial losses since our inception. We anticipate that we will continue to incur significant financial losses for the foreseeable future. • **There is substantial doubt about our ability to continue as a going concern. •** We have never generated revenue from product sales and may never be profitable. • We will need substantial additional funding, and if we are unable to raise capital when needed, we could be forced to delay, reduce or terminate our product discovery and development programs or commercialization efforts. • Our business is highly dependent on the success of our lead product candidate, BT- 001. If we are unable to successfully complete clinical development, obtain regulatory ~~approval~~ **marketing authorization** for or commercialize BT- 001 **, successfully complete our real world evidence programs** , or if we experience delays in doing so, our business will be materially harmed. • ~~The failure of~~ **If physicians are not willing to change current practices to adopt BT- 001 or if** our products **otherwise fail** ~~, if approved,~~ to achieve and maintain market acceptance ~~would cause~~ **, if authorized for marketing,** our business, financial condition and results of operation ~~to~~ **would** be materially and adversely affected. • Competitive products may reduce or eliminate the commercial opportunity for our product candidates, if ~~approved~~ **authorized for marketing** . If our competitors develop technologies or product candidates more rapidly than we do, or their technologies or product candidates are more effective or safer than ours, our ability to develop and successfully commercialize our product candidates may be adversely affected. • If we are unable to develop our sales, marketing and distribution capability on our own or through collaborations with marketing partners, we will not be successful in commercializing ~~our~~ **any** product ~~candidates~~ **candidate** ~~, if approved~~ **authorized for marketing** . • Any failure to offer high- quality patient support **or support to HCPs prescribing our product** may adversely affect our relationships with our existing and prospective patients, and in turn our business, results of operations and financial condition. • We may in the future enter into collaborations, in- licensing arrangements, joint ventures, or strategic alliances with third parties that may not result in the development of commercially viable products or the generation of significant future revenues. • We depend on our senior management team, and the loss of one or more of our executive officers or key employees or an inability to attract and retain highly skilled employees could adversely affect our business ~~. • Risks Related to our Intellectual Property and Potential Litigation • Failure to protect or enforce our intellectual property rights could harm our business and results of operations~~ . • Risks Related to Discovery and Development • Our current product candidates are in various stages of development. Our product candidates may fail in development or suffer delays that adversely affect their commercial viability. If we fail to obtain or maintain FDA de novo classification or clearance to market and sell ~~our~~ BT- 001 ~~digital therapeutic~~ **, or other product candidates** , or if such classification or clearance is delayed **, or if the FDA limits our intended use or limits the clinical data included in our labeling** , our business will be materially harmed. • The clinical trial process required to obtain marketing authorizations for our product candidates is lengthy and expensive with uncertain outcomes. If clinical trials of any of our digital therapeutic applications in development fail to produce results necessary to support regulatory marketing authorization or clearance in the United States or, with respect to our current or future products, elsewhere, we will be unable to commercialize these products and may incur additional costs or experience delays in completing, or ultimately be unable to complete, the commercialization of those products. • Enrollment and retention of patients in clinical trials is an expensive and time- consuming process and could be made more difficult or rendered impossible by multiple factors outside our control ~~. • If patients or physicians are not willing to change current practices to adopt our BT- 001 digital therapeutic, if granted authorization for marketing, our future product candidates may fail to gain increased market acceptance, and our business will be adversely affected~~ . • Our long- term growth depends on our ability to enhance our digital therapeutic products, expand our indications and develop and commercialize additional products once granted marketing authorization ~~and~~ **or** clearance. • ~~Risk~~ **Risks Related to our Intellectual Property and Potential Litigation • We may be subject to legal proceedings and litigation, including intellectual property and privacy disputes, which are costly to defend and could materially harm our business and results of operations. • Failure to establish, protect or enforce our intellectual property rights could harm our business and results of operations. • Risks** Related to Government Regulation • Our products and operations are subject to extensive government regulation and oversight both in the United States and abroad, and our failure to comply with applicable requirements could harm our business. • We may not receive the necessary de novo classification grant for ~~our~~ BT- 001 ~~digital therapeutic~~ or clearances for future expanded indications of ~~our~~ BT- 001 ~~digital therapeutic product candidate~~ , and failure to timely obtain these regulatory authorizations would adversely affect our ability to grow our business. • Risks Related to Healthcare Laws and Regulations • The insurance coverage and reimbursement status of newly- ~~approved~~ **authorized** products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for any of our product candidates, if ~~approved~~ **authorized for marketing** , could limit our ability to market those products and decrease our ability to generate revenue. • ~~We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws,~~

~~false claims laws health information privacy and security laws, and other health care laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties. • Risk~~ **Risks** Related to our Legal and Regulatory Environment • Failure to comply with anti- bribery, anti- corruption and anti- money laundering laws could subject us to penalties and other adverse consequences. • Federal, state and local employment- related laws and regulations could increase our cost of doing business and subject us to fines and lawsuits. • Risks Related to ~~the recently completed Business Combination • If we fail to establish and maintain effective internal control over financial reporting, we may not be able to accurately report our financial results, which may cause investors to lose confidence in our reported financial information and may lead to a decline in the market price of our stock. • Risk Related to Our Organizational Structure • Our executive chairman of the board of directors, David Perry, and our chief executive officer, president and director, Kevin Appelbaum, together will have significant influence over the company. • Risk Related to~~ Our Common Stock • The price of our common stock may be volatile. • Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price. ~~Risk Related to Our Business~~ We are a clinical- stage digital therapeutics company with a limited operating history. We were formed in April 2015 and our operations to date have been limited. We have not yet demonstrated an ability to generate revenues, obtain regulatory ~~approvals~~ **marketing authorizations** , manufacture any product on a commercial scale or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. We have no products ~~approved~~ **authorized** for commercial sale and have not generated any revenue from product sales to date, nor do we expect to generate any revenue **until sometime in 2023 upon commercialization** ~~from product sales for the next few years~~ , if ~~ever~~ **BT- 001 is authorized by the FDA** . We will continue to incur significant research and development and other expenses related to our preclinical and clinical development **, pre- commercialization activities** and ongoing operations. As a result, we are not profitable and have incurred losses in each period since our inception. Net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital. Our net loss was $ **39. 8 million and $** 40. 3 million for the ~~year~~ **twelve months** ended December 31, **2022 and** 2021 **, respectively** . As of December 31, ~~2021~~ **2022** , we had an accumulated deficit of $ ~~71~~ **111** . ~~7~~ **5** million. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of, and seek regulatory ~~approvals~~ **marketing authorizations** for, our product candidates. We anticipate that our expenses will increase substantially if, and as, we: • advance our lead product candidate, BT- 001, through ~~clinical development~~ **commercialization, if authorized by the FDA** ; • advance our pilot stage product candidates into clinical development; • seek to identify, acquire and develop additional product candidates, including through business development efforts to invest in or in-license other technologies or product candidates; • hire additional **regulatory,** clinical, quality control, medical, scientific and other technical personnel to support our clinical operations; • expand our operational, financial and management systems and ~~increases~~ **increase** personnel to support our operations; • meet the requirements and demands of being a public company; • maintain, expand and protect our intellectual property portfolio; • seek regulatory ~~approvals~~ **authorizations** for any product candidates that successfully complete clinical trials; and • **continue to** undertake any pre- commercialization activities to establish sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory ~~approval~~ **authorization** . Digital therapeutic product development entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate efficacy, gain regulatory ~~approval~~ **marketing authorization** , secure market access and reimbursement and become commercially viable and therefore any investment in our company is highly speculative. Additionally, our expenses could increase beyond our expectations if we are required by the FDA, or other regulatory authorities to perform clinical trials in addition to those that we currently expect, or if there are any delays in establishing appropriate arrangements for or in completing our clinical trials or the development of any of our product candidates. You should consider our prospects, factoring in the costs, uncertainties, delays and difficulties frequently encountered by companies in clinical development, especially clinical- stage digital therapeutics companies such as us. Any predictions you make about our future success or viability may not be as accurate as they would otherwise be if we had a longer operating history or a history of successfully developing and commercializing digital therapeutics products. We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives. **We have incurred significant financial losses since our inception. Our net loss was $ 39. 8 million and $ 40. 3 million for the twelve months ended December 31, 2022 and 2021, respectively, and we had an accumulated deficit of $ 111. 5 million as of December 31, 2022. Moreover, we anticipate that we will continue to incur significant financial losses for the foreseeable future. Our existing cash and cash equivalents of $ 15. 7 million as of December 31, 2022 is expected to fund our operations through the first quarter of 2023. Accordingly, there is substantial doubt about our ability to continue as a going concern. Our financial statements included elsewhere in this Annual Report do not include any adjustments that might result from the outcome of this uncertainty. Additionally, our independent registered public accounting firm' s report for the year ended December 31, 2022 contains an explanatory paragraph that expresses substantial doubt about our ability to continue as a going concern. We plan to seek additional funding through various financing sources, including the sale of equity and / or debt securities, and we are exploring other non- dilutive financing options. There can be no assurance that any future financing efforts will be successful. If we are unable to obtain additional funding, or if we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, reduce or terminate our product development programs or plans for commercialization. We could also be required to limit or terminate our operations, make reductions in our workforce, discontinue our development programs, liquidate all or a portion of our assets or pursue other strategic alternatives, in which case investors may not receive any return on their investment and may lose their entire investment.** Our ability to become and remain profitable depends on our ability to generate revenue or execute other business development arrangements. We do not expect to generate significant revenue, if any, unless and until we are able to obtain regulatory ~~approval~~ **authorization** for, and

successfully commercialize the product candidates we are developing or may develop. Successful commercialization will require achievement of many key milestones, including demonstrating safety and efficacy in clinical trials, obtaining regulatory ~~approval~~ **authorization** for these product candidates, developing, marketing and selling those products for which we may obtain regulatory ~~approval~~ **authorization** , satisfying any post- marketing requirements and obtaining **favorable** reimbursement for our products from private insurance or government payers. Because of the uncertainties and risks associated with these activities, we are unable to accurately and precisely predict the timing and amount of revenues, the extent of any further losses or if or when we might achieve profitability. We may never succeed in these activities and, even if we do, we may never generate revenues that are significant enough for us to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable may depress the market price of our common stock and could impair our ability to raise capital, expand our business, diversify our product offerings or continue our operations. If we continue to suffer losses as we have since inception, investors may not receive any return on their investment and may lose their entire investment. Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts to continue the clinical and preclinical development of our product candidates, **and** ~~including the program~~ for ~~our leading product candidate~~ **pre- commercialization activities for** BT- 001. We will need to raise additional capital to complete our currently planned clinical trials and any future clinical trials **for our product candidates and any future clinical trials** . Other unanticipated costs may arise in the course of our development efforts. If we are able to gain marketing ~~approval~~ **authorization** for product candidates that we develop, we will require significant additional amounts of funding in order to launch and commercialize such product candidates. We cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of any product candidate we develop and we may need substantial additional funding to complete the development and commercialization of our product candidates. Our future need for additional funding depends on many factors, including: • the scope, progress, results and costs of researching and developing our current product candidates, as well as other additional product candidates we may develop and pursue in the future; • the timing of, and the costs involved in, obtaining marketing ~~approvals~~ **authorization** for our product candidates and any other additional product candidates we may develop and pursue in the future; • the number of future product candidates that we may pursue and their development requirements; • the **translation of product (s) in non- English markets; • the costs of regulatory filings in foreign countries; • the** costs of commercialization activities for our product candidate **, if authorized** , including the costs and timing of establishing product sales, marketing, and distribution capabilities; • subject to receipt of regulatory ~~approval~~ **authorization** , revenue, if any, received from commercial sales of our product candidates; • the extent to which we in- licenses or acquire rights to other products, product candidates or technologies; • our headcount growth and associated costs as we expand our research and development and establish a commercial infrastructure; • the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights, including enforcing and defending intellectual property related claims; and • the costs of operating as a public company. We cannot be certain that additional funding will be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, reduce or terminate our product development programs or plans for commercialization. We believe that we will be able to fund our operating expenses and capital expenditure requirements ~~into~~ **through the first quarter of** 2023. Our estimate may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Further, changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned. Due to the significant resources required for the development of our pipeline, and depending on our ability to access capital, we must prioritize the development of certain product candidates over others. We may fail to expend our limited resources on product candidates or indications that may have been more profitable or for which there is a greater likelihood of success. We currently have one ~~clinical- stage~~ product candidate **for which a de novo classification request is pending with the FDA** as well as several other product candidates that are at various earlier stages of development. We seek to maintain a process of prioritization and resource allocation to maintain an optimal balance between aggressively pursuing our **pre- commercialization efforts for our** more advanced ~~clinical- stage~~ product candidate, BT- 001, and ensuring the development of additional potential product candidates. Due to the significant resources required for the development of our product candidates **and current limited runway for funding** , we must decide which product candidates to pursue and advance and the amount of resources to allocate to each. Our decisions concerning the allocation of research, development, collaboration, management and financial resources toward particular product candidates or therapeutic areas may not lead to the development of any viable commercial products and may divert resources away from better opportunities. If we make incorrect determinations regarding the viability or market potential of any of our product candidates or misread trends in the pharmaceutical industry, in particular for cardiometabolic disorders, our business, financial condition, and results of operations could be materially adversely affected. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other product candidates or other diseases and disease pathways that may later prove to have greater commercial potential than those we choose to pursue, or relinquish valuable rights to such product candidates through collaboration, licensing, or other royalty arrangements in cases in which it would have been advantageous for us to invest additional resources to retain sole development and commercialization rights. Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates. We expect our expenses to increase in connection with our planned operations. Unless and until we can generate a substantial amount of revenue from our product candidates, we expect to finance our future cash needs through public or private equity offerings, debt financings, collaborations, licensing arrangements or other sources, or any combination of the foregoing. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans. To the extent that we raise additional capital

through the sale of common stock, convertible securities or other equity securities, your ownership interest may be diluted, and the terms of these securities could include liquidation or other preferences and anti- dilution protections that could adversely affect your rights as a common stockholder. In addition, debt financing, if available, may result in fixed payment obligations and may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures, creating liens, redeeming stock or declaring dividends, that could adversely impact our ability to conduct our business. In addition, securing financing could require a substantial amount of time and attention from our management and may divert a disproportionate amount of their attention away from day- to- day activities, which may adversely affect management' s ability to oversee the development of our product candidates. If we raise additional capital through collaborations or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional capital when needed, we may be required to delay, reduce or terminate our product discovery and development programs or commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ~~ourself~~ **ourselves** . The amount of our future losses is uncertain and our quarterly and annual operating results may fluctuate significantly or fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline. Our quarterly and annual operating results may fluctuate significantly in the future due to a variety of factors, many of which are outside of our control and may be difficult to predict, including the following: • the timing and success or failure of our 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 or **as a result of the ongoing COVID- 19 pandemic or increasing global economic instability; • our ability to successfully recruit and retain subjects for clinical trials, and any delays caused by difficulties in such efforts, including** as a result of the ongoing COVID- 19 pandemic; • our ability to ~~successfully recruit and retain subjects for clinical trials, and any delays caused by difficulties in such efforts, including as a result of the ongoing COVID- 19 pandemic; • our ability to~~ obtain marketing ~~approval~~ **authorization** for our product candidates and the timing and scope of any such ~~approvals~~ **marketing authorizations** we may receive; • the timing and cost of, and level of investment in, research and development activities relating to our product candidates, which may change from time to time; • our ability to attract, hire and retain qualified personnel; • expenditures that we will or may incur to develop additional product candidates; • the level of demand for our product candidates should they receive ~~approval~~ **marketing authorization** , which may vary significantly; • the risk / benefit profile, cost and reimbursement policies with respect to our product candidates, if ~~approved~~ **authorized for marketing** , and existing and potential future therapeutics that compete with our product candidates; • the changing and volatile U. S. and global economic environments; and • future accounting pronouncements or changes in our accounting policies. 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. 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 operating results or revenue 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 any previously publicly stated guidance we may provide. To date, we as an organization have not **obtained marketing authorization** ~~completed any clinical trials or~~ **for** ~~development of~~ any product candidates. Our future success and ability to generate revenue from our ~~lead~~ product candidates ~~,~~ is dependent on our ability to ~~successfully develop,~~ obtain regulatory ~~approval~~ **marketing authorization** for and commercialize BT- 001. We completed ~~enrollment in~~ our ~~potentially~~ pivotal clinical trial for BT- 001 in ~~November~~ **July** ~~2021~~ **2022** and ~~announced primary endpoint data~~ **our de novo classification request was accepted for substantive review by the FDA** in ~~March~~ **October** 2022. If BT- 001 encounters ~~efficacy problems, development delays or~~ regulatory issues or other problems, the development plans for our other product candidates and business would be materially harmed. We may not have the financial resources to continue development of our product candidates if **our de novo classification request pending with the FDA for** BT- 001 experiences any issues that delay or prevent regulatory ~~approval~~ **authorization** of, or our ability to commercialize, BT- 001, including: • our inability to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that BT- 001 is safe and effective; • insufficiency of our financial and other resources to complete the necessary clinical trials and preclinical studies; • negative or inconclusive results **or differing interpretations with regulatory authorities of the data** from our clinical trials, preclinical studies or the clinical trials of others for product candidates similar to ours, leading to a decision or requirement to conduct additional clinical trials or preclinical studies or abandon a program; • product- related adverse events experienced by subjects in our clinical trials, including unexpected results, or by individuals using products similar to BT- 001; • delays in enrolling subjects in clinical trials; • high drop- out rates of subjects from clinical trials; • ~~poor effectiveness of BT- 001 during clinical trials; •~~ greater than anticipated clinical trial or manufacturing costs; • delays in ~~submitting a~~ **the review of our** de novo ~~application~~ **classification request by the FDA** , ~~or~~ **delays in submitting** comparable foreign applications or delays or failure in obtaining the necessary approvals from regulators to commence a clinical trial or a suspension or termination, or hold, of a clinical trial once commenced; • conditions imposed by the FDA, the European Medicines Agency ~~(" EMA")~~ , or comparable foreign regulatory authorities regarding the scope or design of our clinical trials; **or** • delays and changes in regulatory requirements, policy and guidelines, including the imposition of additional regulatory oversight around clinical testing generally or with respect to our ~~therapies~~ **product candidates** in particular ~~; or • varying interpretations of data by the FDA, EMA and comparable foreign regulatory authorities~~ . Our current business strategy is highly dependent on our products potentially achieving FDA authorization for commercial distribution and maintaining market acceptance. Market acceptance and adoption of our products depends on educating people with cardiometabolic conditions, as well as payers, health plans and government entities, as to the distinct features, clinical impact, cost savings, and other benefits

of our products. If we are not successful in demonstrating to physicians who treat potential patients the benefits of our products, if ~~approved~~ **authorized for marketing**, or if we are not able to achieve the support of insurance carriers for our products, our business, financial condition and results of operation would be materially and **adversely affected** ~~,which could harm our business,operating results,prospects or financial condition~~ .Our primary strategy to grow our revenue is to drive the adoption of our BT- 001 digital therapeutic,if granted marketing authorization,by physicians to assist their patients in improving glycemic control ~~by lowering HbA1c~~ .Physicians may choose not to adopt our digital therapeutic products for a number of reasons,including:• lack of availability of adequate third- party payer coverage or reimbursement;• lack of experience with our product;• our inability to convince key opinion leaders to recommend our products;• perceived inadequacy of evidence supporting clinical benefits,safety or cost- effectiveness of our product;• liability risks generally associated with the use of new products;and • the training required to use new products. ~~We~~ **For our lead product candidate,BT- 001,if authorized for marketing,we intend to** focus our sales,marketing and training efforts primarily on primary care physicians.However,physicians from other disciplines,such as endocrinologists,as well as other medical professionals,such as nurse practitioners and physician assistants,are often the initial point of contact for patients with diabetes management needs.We believe that educating physicians in these disciplines and other medical professionals about the clinical merits,patient benefits and safety profile of our digital therapeutic products is an element of increasing product adoption. ~~If~~ **However,if** additional primary care physicians or other medical professionals do not appreciate and recommend the benefits of our digital therapeutic for any reason,including those listed above,our ability to execute our growth strategy will be impaired,and our business may be ~~adversely affected.In~~ adversely affected. In addition, our products may be perceived by patients and healthcare providers to be more complicated or less effective than traditional approaches, and people may be unwilling to change their current health regimens. Moreover, we believe that healthcare providers tend to be slow to change their medical treatment practices because of perceived liability risks **or new workflow processes** arising from the use of new products and the uncertainty of third- party reimbursement. Accordingly, healthcare providers may not recommend our products until there is sufficient evidence to convince them to alter their current approach **. Additionally, patients may not be able to adopt or may choose not to adopt our digital therapeutic if, among other potential reasons, they are worried about potential adverse effects of use of our digital therapeutic or they are unable to obtain adequate third- party coverage or reimbursement. If our products fail to achieve market acceptance for any reason, our business, financial condition and results of operation would be materially and adversely affected** . The clinical and commercial landscapes for the treatment of cardiometabolic diseases are highly competitive and subject to rapid and significant technological change. We face competition with respect to our indications for our product candidates from major pharmaceutical companies, specialty pharmaceutical companies, biotechnology companies and potentially other technology companies. There are a number of large pharmaceutical and biotechnology companies that currently market and sell drugs or are pursuing the development of drug candidates for the treatment of the indications that we are pursuing. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization. In addition, technology companies are increasingly exploring the potential for digital products to manage and treat cardiometabolic diseases that could compete with our product candidates, if ~~approved~~ **authorized for marketing** . Our competitors may have significantly greater financial resources, established presence in the market, expertise in research and development, manufacturing, preclinical and clinical testing, obtaining regulatory ~~approvals~~ **marketing authorizations** and reimbursement and marketing ~~approved~~ **commercialized** products than we do. Accordingly, our competitors may be more successful than we may be in obtaining regulatory ~~approval~~ **marketing authorization** for therapies and achieving widespread market acceptance. Our competitors' products may be more effective, or more effectively marketed and sold, than any product candidate we may commercialize and may render our therapies obsolete or non- competitive before we can recover development and commercialization expenses. If any of our product candidates, including BT- 001, is ~~approved~~ **authorized for marketing** , it could compete with a range of therapeutic treatments that are in development. If we obtain ~~approval~~ **marketing authorization** for any of our product candidates, we may face competition based on many different factors, including the efficacy, safety and tolerability of our products, the ease with which our products can be administered, the timing and scope of regulatory ~~approvals~~ **marketing authorization** for these products, the availability and cost of manufacturing, marketing and sales capabilities, price, reimbursement coverage and patent position. Existing and future competing products could present superior treatment alternatives, including being more effective, safer, less expensive or marketed and sold more effectively than any product we may develop. Competitive products may make any product we develop obsolete or noncompetitive before we recover the expense of developing and commercializing our product candidates. Such competitors could also recruit our employees, which could negatively impact our level of expertise and our ability to execute our business plan. In addition, our competitors may obtain patent protection or FDA ~~approval~~ **approvals and marketing authorizations** and commercialize products more rapidly than we do, which may impact future ~~approvals~~ **authorizations or clearances we may seek** or sales of any of our product candidates that receive regulatory ~~approval~~ **marketing authorization or clearance** . If the FDA approves the commercial sale of any of our product candidates, we will also be competing with respect to marketing capabilities and manufacturing efficiency. We expect competition among products will be based on product efficacy and safety, the timing and scope of regulatory ~~approvals~~ **authorizations or clearances** , marketing and sales capabilities, product price, reimbursement coverage by government and private third- party payers, regulatory exclusivities and patent position. Our profitability and financial position will suffer if our product candidates receive regulatory ~~approval~~ **marketing authorization** but cannot compete effectively in the marketplace. Additionally, mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early- stage companies may also prove to be significant competitors, particularly as the develop disruptive therapies through collaborative arrangements with large and established companies. These third parties compete with us in

recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites, as well as in acquiring technologies complementary to, or necessary for, our programs. Acquisitions and investments could result in operating difficulties, dilution and other harmful consequences that may adversely impact our business, results of operations and financial condition. We may in the future make acquisitions to add complementary companies, products, technologies, or revenue. These transactions could be material to our results of operations and financial condition. We may also evaluate and enter into discussions regarding a wide array of potential strategic transactions. The identification of suitable acquisition candidates can be difficult, time- consuming and costly, and we may not be able to complete acquisitions on favorable terms, if at all. The process of integrating an acquired company, business or technology may create unforeseen operating difficulties and expenditures. The areas where we face risks include: • loss of key employees of the acquired company and other challenges associated with integrating new employees into our culture, as well as reputational harm if integration is not successful; • diversion of management time and focus from operating our business to addressing acquisition integration challenges; • implementation or remediation of controls, procedures, and policies at the acquired company; • difficulties in integrating and managing the combined operations, technologies, technology platforms and products of the acquired companies and realizing the anticipated economic, operational and other benefits in a timely manner, which could result in substantial costs and delays or other operational, technical or financial problems; • integration of the acquired company' s accounting, human resource and other administrative systems, and coordination of products, engineering and sales and marketing function; • assumption of contractual obligations that contain terms that are not beneficial to us, require us to license or waive intellectual property rights, or increase our risk for liabilities; • failure to successfully further develop the acquired technology or realize our intended business strategy; • uncertainty of entry into markets in which we have limited or no prior experience or in which competitors have stronger market positions; • unanticipated costs associated with pursuing acquisitions; • failure to find commercial success with the products or services of the acquired company; • difficulty of transitioning the acquired technology onto our existing platforms and maintaining the security standards for such technology consistent with our other products; • failure to successfully onboard patients or maintain brand quality of acquired companies; • responsibility for the liabilities of acquired businesses, including those that were not disclosed to us or exceed our estimates, as well as, without limitation, liabilities arising out of their failure to maintain effective data protection and privacy controls and comply with applicable regulations; • inability to maintain our internal standards, controls, procedures, and policies; • failure to generate the expected financial results related to an acquisition on a timely manner or at all; • difficulties in complying with antitrust and other government regulations; • challenges in integrating and auditing the financial statements of acquired companies that have not historically prepared financial statements in accordance with GAAP; • potential accounting charges to the extent intangibles recorded in connection with an acquisition, such as goodwill, trademarks, patient relationships or intellectual property, are later determined to be impaired and written down in value; and • failure to accurately forecast the impact of an acquisition transaction. Future acquisitions could also result in expenditures of significant cash, dilutive issuances of our equity securities, the incurrence of debt, restrictions on our business, contingent liabilities, amortization expenses or write- offs of goodwill, any of which could harm our financial condition. In addition, any acquisitions we announce could be viewed negatively by patients. Additionally, competition within our industry for acquisitions of business, technologies and assets may become intense. Even if we are able to identify an acquisition that we would like to consummate, we may not be able to complete the acquisition on commercially reasonable terms or the target may be acquired by another company. We may enter into negotiations for acquisitions that are not ultimately consummated. Those negotiations could result in diversion of management time and significant out- of- pocket costs. If we fail to evaluate and execute acquisitions successfully, we may not be able to realize the benefits of these acquisitions, and our operating results could be harmed. If we are unable to successfully address any of these risks, our business, financial condition or operating results could be harmed. **If we are unable to develop our sales, marketing and distribution capability on our own or through collaborations with marketing partners, we will not be successful in commercializing our product candidates, if authorized for marketing.** We **are** currently **commencing pre- commercialization activities but** have ~~no~~ **not completed the build- out of our** marketing, sales or distribution capabilities. We intend to establish a sales and marketing organization, to commercialize our product candidates, if ~~approved~~ **authorized for marketing**. These efforts will require substantial additional resources, some or all of which may be incurred in advance of any approval of the product candidate. Any failure or delay in the development of our sales, marketing and distribution capabilities would adversely impact the commercialization of our product candidates, if ~~approved~~ **authorized for marketing**. Factors that may inhibit our efforts to commercialize our product candidates, if ~~approved~~ **authorized for marketing**, include: • our inability to recruit and retain adequate numbers of effective sales and marketing personnel; • the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe our products, if ~~approved~~ **authorized for marketing**; • the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and • unforeseen costs and expenses associated with creating an independent sales and marketing organization. With respect to our existing and future product candidates, we may choose to collaborate with third parties that have direct sales forces and established distribution systems to serve as an alternative to our own sales force and distribution systems. Our future product revenue may be lower than if we directly marketed or sold our product candidates, if ~~approved~~ **authorized for marketing**. In addition, any revenue we receive will depend in whole or in part upon the efforts of these third parties, which may not be successful and are generally not within our control. If we are not successful in commercializing any ~~approved~~ products **authorized for marketing**, our future product revenue will suffer and we may incur significant additional losses. If we are unable to achieve widespread acceptance of our products, if ~~approved~~ **authorized for marketing**, our revenue growth could be slower than we expect, and our business may be adversely affected. We expect to generate revenue from physicians prescription of our products, if ~~approved~~ **authorized for marketing**, for patients. As a result, widespread acceptance, prescription and use of our products, if ~~approved~~ **authorized for marketing**, is critical to our future growth and success. If the market fails to grow

or grows more slowly than we currently anticipate, demand for **any of** our **marketed** products ~~, if approved,~~ could be negatively affected and our revenue may grow more slowly than we expect and our business may be adversely affected. Demand for ~~our~~ **any** products **we market** , if ~~approved~~ **authorized by the FDA** , is affected by a number of factors, many of which are beyond our control. Some of these potential factors include: • awareness of our products and the adoption of prescription CBT; • ease of adoption and use; • platform experience; • performance; • brand; • security and privacy; ~~and~~ • pricing **; and • reimbursement** . In implementing and using our products, our patients will depend on our patient support to resolve issues in a timely manner. We may be unable to respond quickly enough to accommodate short- term increases in demand for patient support. Increased patient demand for support could increase costs and adversely affect our results of operations and financial condition. Any failure to maintain high- quality patient support, or a market perception that we do not maintain high- quality patient support, could adversely affect patient satisfaction or the willingness of physicians to prescribe our products, and in turn our business, results of operations, and financial condition. If we fail to effectively manage our..... could negatively affect our business performance. In the ordinary course of our business, we may enter into collaborations, in- licensing arrangements, joint ventures, or strategic alliances to develop proposed products and to pursue new markets. In the future, proposing, negotiating, and implementing collaborations, in- licensing arrangements, joint ventures, strategic alliances, or partnerships may be a lengthy and complex process. Other companies, including those with substantially greater financial, marketing, sales, technology or other business resources, may compete with us for these opportunities or arrangements. We may not identify, secure or complete any such transactions or arrangements in a timely manner, on a cost- effective basis, on acceptable terms or at all, and may not realize the anticipated benefits of any such transaction or arrangement. Additionally, with respect to current and future collaborations, we may not be in a position to exercise sole decision- making authority regarding the transaction or arrangement, which could create the potential risk of creating impasses on decisions, and our collaborators may have economic or business interests or goals that are, or that may become, inconsistent with our business interests or goals. It is possible that conflicts may arise with our collaborators, such as conflicts concerning the achievement of performance milestones, or the interpretation of significant terms under any agreement, such as those related to financial obligations or the ownership or control of intellectual property developed during the collaboration. If any conflicts arise with our current or future collaborators, they may act in their self- interest, which may be adverse to our best interest, and they may breach their obligations to us. In addition, we have limited control over the amount and timing of resources that our current collaborators or any future collaborators devote to our collaborators' or our future products. Disputes between us and our collaborators may result in litigation or arbitration which would increase our expenses and divert the attention of our management. Further, these transactions and arrangements are contractual in nature and may be terminated or dissolved under the terms of the applicable agreements and, in such event, we may not continue to have rights to the products relating to such transaction or arrangement or may need to purchase such rights at a premium. We could suffer disruptions, outages, defects, and other performance and quality problems with our platform or with the cloud and internet infrastructure on which ~~it relies~~ **we rely** . Our business depends on our platform to be available without disruption. We have experienced, and may in the future experience, disruptions, outages, defects, and other performance and quality problems with our platform. We have also experienced, and may in the future experience, disruptions, outages, defects, and other performance and quality problems with the cloud and internet infrastructure on which our platform relies. These problems can be caused by a variety of factors, including introductions of new functionality, vulnerabilities and defects in proprietary and open source software, human error or misconduct, capacity constraints, design limitations, or denial of service attacks or other security- related incidents. Further, if our contractual and other business relationships with our cloud service providers are terminated, suspended, or suffer a material change to which we are unable to adapt, such as the elimination of services or features on which we depend, we could be unable to provide our platform and could experience significant delays and incur additional expense in transitioning patients to a different cloud service provider. Any disruptions, outages, defects, and other performance and quality problems with our platform or with the cloud and internet infrastructure on which ~~it relies~~ **we rely** , or any material change in our contractual and other business relationships with our cloud services providers, could result in reduced use of our platform, increased expenses, including service credit obligations, and harm to our brand and reputation, any of which could have a material adverse effect on our business, financial condition, and results of operations. Our ~~success depends largely upon the continued services of our key executive officers. These executive officers are at- will employees and therefore they may terminate employment with us at any time with no advance notice. We rely on our leadership team in the areas of operations, clinical and software development, information security, marketing, compliance and general and administrative functions. From time to time, there may be changes in our executive management team resulting from the hiring or departure of executives, which could disrupt our business. The loss of one or more of the members of our senior management team, or other key employees, could harm our business. The replacement of one or more of our executive officers or other key employees would likely involve significant time and costs and may significantly delay or prevent the achievement of our business objectives. To continue to execute our growth strategy, we also must attract and retain highly skilled personnel. Competition is intense for qualified professionals. We may not be successful in continuing to attract and retain qualified personnel. We have from time to time in the past experienced, and we expect to continue to experience in the future, difficulty in hiring and retaining highly skilled personnel with appropriate qualifications. The pool of qualified personnel with experience working in the healthcare market is limited overall. In addition, many of the companies with which we compete for experienced personnel have greater resources than we have. Additionally, our success is dependent on our ability to evolve our culture, align our talent with our business needs, engage our employees and inspire our employees to be open to change and innovate. Our business would be adversely affected if we fail to adequately plan for succession of our executives and senior management, or if we fail to effectively recruit, integrate, retain and develop key talent and / or align our talent with our business needs, in light of the current rapidly changing environment. Our~~ business could be disrupted by catastrophic events and man- made problems, such as power disruptions, data security breaches, and terrorism.

Our platform and the cloud- based infrastructure on which our platform relies are vulnerable to damage or interruption from the occurrence of any catastrophic event, including earthquake, fire, flood, tsunami, or other weather event, power loss, telecommunications failure, software or hardware malfunction, cyber- attack, war, terrorist attack, incident of mass violence or disease, such as the **ongoing** COVID- 19 pandemic, and similar events, which could result in lengthy interruptions in access to our platform. In addition, acts of terrorism, including malicious internet- based activity, could cause disruptions to the internet or the economy as a whole. Even with our disaster recovery arrangements, access to our platform could be interrupted. If our systems were to fail or be negatively impacted as a result of a natural disaster or other event, our ability to deliver our platform and products to our patients would be impaired or we could lose critical data. If we are unable to develop adequate plans to ensure that our business functions continue to operate during and after a disaster, and successfully execute on those plans in the event of a disaster or emergency, our business, financial condition, and results of operations would be harmed. We have implemented a disaster recovery program that allows us to move **mobile and** website traffic to a backup data center in the event of a catastrophe. This allows us the ability to move traffic in the event of a problem, and the ability to recover in a short period of time. However, to the extent our disaster recovery program does not effectively support the movement of traffic in a timely or complete manner in the event of a catastrophe, our business and results of operations may be harmed. We do not carry business interruption insurance sufficient to compensate us for the potentially significant losses, including the potential harm to our business, financial condition and results of operations that may result from interruptions in access to our platform as a result of system failures **. Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations. Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. A severe or prolonged economic downturn may cause extreme volatility and disruptions in the capital and credit markets and could result in a variety of risks to our business and our ability to raise additional capital when needed on acceptable terms, if at all. Additionally, our obligations to repay principal and interest on our indebtedness make us vulnerable to economic or market downturns. Geopolitical developments, or the perception that any of them could occur, may lead to worldwide economic and legal uncertainty, including significant volatility in global stock markets and currency exchange rates, and increasingly divergent laws and regulations. In February 2022, armed conflict escalated between Russia and Ukraine. The sanctions announced by the U. S. and other countries against Russia since February 2022 include restrictions on selling or importing goods, services, or technology in or from affected regions and travel bans and asset freezes impacting connected individuals and political, military, business, and financial organizations in Russia. The U. S. and other countries could impose wider sanctions and take other actions should the conflict further escalate. It is not possible to predict the broader consequences of this conflict, which could include further sanctions, embargoes, regional instability, prolonged periods of higher inflation, geopolitical shifts, and adverse effects on macroeconomic conditions, currency exchange rates, and financial markets, all of which could have a material adverse effect on our business, financial condition, and results of operations. Any of the foregoing could harm our business, and we cannot anticipate all the ways in which the current economic climate and financial market conditions could adversely impact our business** . Our Loan Agreement with Hercules Capital contains restrictions that limit our flexibility in operating our business. In August 2021, we entered into a loan and security agreement (the **“ "** Loan Agreement **” "**) with Hercules Capital, Inc. (**“ "** Hercules Capital **” "**) as agent and lender. The Loan Agreement provides for an up to $ 50. 0 million senior secured term loan facility (the **“ "** Term Loan Facility **” "**). The Loan Agreement is secured by a lien on substantially all of our assets, including, but not limited to, shares of our subsidiaries, our current and future intellectual property, insurance, trade and intercompany receivables, inventory and equipment and contract rights. The Loan Agreement requires us to meet specified minimum cash requirements, as described below, and contains various affirmative and negative covenants that limit our ability to engage in specified types of transactions. These covenants, which are each subject to customary exceptions, limit our ability to, without Hercules Capital’ s prior written consent, effect any of the following, among other things: • sell, lease, transfer or otherwise dispose of certain assets; • acquire another company or business or enter into a merger or similar transaction with third parties; • incur additional indebtedness; • make investments; • enter into certain outbound licenses of intellectual property; • encumber or permit liens on certain assets; and • pay dividends and make other restricted payments with respect to our capital stock. Our board of directors ~~(the" Board")~~ or management team could believe that taking any one of these actions would be in our best interests and the best interests of our stockholders. If that were the case and if we were unable to complete any of these actions because Hercules Capital does not provide its consent, that could adversely impact our business, financial condition and results of operations. In addition, on or after July 1, 2023, we are required to maintain a minimum aggregate balance of $ 10. 0 million in cash in one or more controlled accounts. Such requirement terminates if we reach certain valuation requirements. These accounts are required to be maintained as cash collateral accounts securing our obligations under the Loan Agreement. While such requirements apply under the Loan Agreement, our ability to use the cash amounts held in these controlled accounts in the operation of our business will be limited. On October 28, 2021, we drew down on $ 10 million of the Term Loan Facility **and in May 2022, we drew down an additional $ 5 million of the Term Loan Facility** . Our ability to draw on the remaining Term Loan Facility is contingent on our compliance with the covenants described above and certain other covenants and milestones. **We did** ~~Even if we meet these conditions, we may elect~~ not **initiate a second pivotal trial prior** to ~~draw on~~ **September 15, 2022 that was required under** the ~~remaining Term~~ Loan ~~Facility~~ **Agreement, and hence, as a result the associated borrowing is no longer available to the Company** . In the event of a default under the Loan Agreement, including, among other things, our failure to make any payment when due or our failure to comply with any provision of the Loan Agreement, subject to customary grace periods, Hercules Capital could elect to declare all amounts outstanding to be immediately due and payable and terminate all commitments to extend further credit. If we are unable to repay the amounts due under the Loan Agreement, Hercules Capital could proceed against the collateral granted to it to secure this indebtedness, which could have an adverse effect on our business, financial condition and results of operations. **Additionally, the Loan Agreement**

contains subjective acceleration clauses that would allow Hercules Capital **to accelerate the scheduled maturities and obligations under the Loan Agreement if they determine that there has been a Material Adverse Change (as defined in the Loan Agreement) in our business, financial condition or the prospect of repayment of any obligations under the Loan Agreement, among other things. In the event a subjective acceleration clause is invoked, the outstanding principal, interest, end of term charge and prepayment penalty under the Loan Agreement would become payable on demand by Hercules Capital. There is no assurance that Hercules Capital will not invoke an acceleration clause in the future, which would have an adverse effect on our business and financial condition. Hercules Capital' s** interests as a lender may not always be aligned with our interests. If our interests come into conflict with those of Hercules Capital, including in the event of a default under the Loan Agreement, Hercules Capital may choose to act in its self- interest, which could adversely affect the success of our current and future collaborative efforts with Hercules Capital. ~~We~~ If we fail to effectively manage our growth,we may be unable to execute our business plan,adequately address competitive challenges or maintain our corporate culture,and our business,financial condition and results of operations would be harmed.The growth and expansion of our business creates significant challenges for our management,operational and financial resources.To effectively manage our growth,we must continue to improve our operational,financial and management processes and systems and to effectively expand,train and manage our employee base.As our organization continues to grow and we are required to implement more complex organizational management structures,we may find it increasingly difficult to maintain the benefits of our corporate culture.This could negatively affect our business performance. may be subject to **certain limitations.Our NOLs could expire unused and be unavailable to offset future income tax liabilities because of their limited duration or because of restrictions under U.S.tax law.NOLs generated in taxable years beginning before January 1,2018 are permitted to be carried forward for 20 taxable years under applicable U.S.federal income tax law.Under current U.S.federal income tax law,NOLs arising in tax years beginning after December 31,2020 may not be carried back.Moreover,NOLs generated in taxable years beginning after December 31,2017 may be carried forward indefinitely.As of December 31,2022,we had NOLs for U.S.federal and state income tax purposes of approximately $ 59.8 million.NOLs generated between January 1,2020 and December 31,2022 for U.S.federal tax reporting purposes of approximately $ 56.7 million have an indefinite life.NOLs generated between January 1,2020 and December 31,2022 for state tax reporting purposes of approximately $ 3.0 million will begin to expire in 2035.In general,under Section 382 of the Internal Revenue Code of 1986,as amended (the" Code"),a corporation that undergoes an" ownership change" (defined under Section 382 of the Code and applicable Treasury Regulations as a greater than 50 percentage point change (by value) in a corporation' s equity ownership by certain stockholders over a rolling three- year period) is subject to limitations on its ability to utilize its pre- change NOLs to offset future taxable income.We have not determined whether the NOLs from our operations are limited under Section 382 of the Code;however,based on a preliminary review of information available,other than the NOL attributes that were carried forward from the Business Combination,the Company does not believe its NOLs are currently limited by Section 382.We may have experienced ownership changes in the past and may experience ownership changes in the future,including as a result of our business combination or subsequent shifts in our stock ownership (some of which are outside our control).Furthermore,our ability to utilize NOLs of companies that we may acquire in the future may be subject to limitations.NOL attributes that were carried forward from our business combination are expected to be subject to the limitations under Section 382.The NOLs subject to that limitation are $ 77 thousand as of December 31,2022 and 2021.There is also a risk that due to regulatory changes,such as suspensions on the use of NOLs or other unforeseen reasons,our existing NOLs could expire or otherwise be unavailable to reduce future income tax liabilities,including for state tax purposes.For these reasons,we may not be able to utilize a material portion of the NOLs reflected on our balance sheet,even if we attain profitability,which could potentially result in increased future tax liability to us and could adversely affect our operating results and financial condition.Changes in tax law may adversely affect us or our investors.The rules dealing with U.S.federal,state and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U.S.Treasury Department.Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock.For example,under Section 174 of the Code,in taxable years beginning after December 31,2021,expenses that are incurred for research and development in the U.S.will be capitalized and amortized,which may have an adverse effect on our cash flow.In recent years,many such changes have been made,and changes are likely to continue to occur in the future.It cannot be predicted whether,when,in what form or with what effective dates tax laws,regulations and rulings may be enacted,promulgated or issued,which could result in an increase in our or our shareholders' tax liability or require changes in the manner in which we operate in order to minimize or mitigate any adverse effects of changes in tax law.Our current product candidates are in various stages of development.Our product candidates may fail in development or suffer delays that adversely affect their commercial viability.If we fail to obtain or maintain FDA de novo classification or clearance to market and sell BT- 001 or other product candidates,or if such classification or clearance is delayed,or if the FDA limits our intended use or limits the clinical data included in our labeling,our business will be materially harmed.** The process of seeking regulatory de novo classification or clearance to market a medical device is expensive and time consuming.There can be no assurance that marketing authorization will be granted. **In October 2022,the FDA notified us that our de novo classification request for BT- 001 was accepted for substantive review.** If we are not successful in obtaining timely ~~de novo classification granting~~ marketing authorization of ~~our~~ BT- 001 ~~digital therapeutic~~ **from the FDA** ,or any of our other product candidates,we may never be able **to pursue authorization by foreign regulatory authorities or** to generate significant revenue and may be forced to cease operations.Specifically,we hope to pursue additional regulatory marketing clearances for ~~our~~ BT- 001 ~~digital therapeutic~~ for additional uses if our first de novo classification is granted.The FDA de novo classification process requires an applicant to

demonstrate the safety and efficacy based,in part,on extensive data,including,but not limited to preclinical,clinical trial,technical,manufacturing and labeling data.The FDA regulatory clearance process requires an applicant to demonstrate the device to be marketed is as safe and effective,that is,substantially equivalent,to a legally marketed device and the de novo classification process requires an applicant to demonstrate the safety and effectiveness of a new device.The FDA can delay,limit or deny de novo classification or clearance of a device for many reasons,including:• we may not be able to demonstrate to the FDA' s satisfaction that our product candidates are safe and effective for their intended use;• the FDA may disagree that our clinical data supports the label and use that we are seeking;and • the FDA may disagree that the data from our preclinical or pilot studies and clinical trials is sufficient to support marketing authorization.Obtaining de novo classification and clearance from the FDA or any foreign regulatory authority could result in unexpected and significant costs for us and consume management' s time and other resources.The FDA could ask us to supplement our submissions,collect additional non- clinical data,conduct additional clinical trials,prepare additional manufacturing data or information or engage in other time- consuming actions,or it could simply deny our applications. **For example,as part of the typical de novo review process as expected by us,in February 2023,we received a Request for Additional Information from the FDA notifying us that,after review of our submission,the FDA determined that additional information is required.The letter outlined the FDA' s view that our submission has a number of deficiencies,classified into major and minor deficiencies.We requested a meeting with the FDA to clarify several of the major deficiencies noted as well as to seek guidance on our options to address them.That meeting also took place in February.During the meeting the FDA provided helpful context,clarifications and guidance,and we are now compiling our response to address the FDA' s comments.We believe we can address the FDA' s questions,and our previously provided guidance that we anticipate FDA' s decision by the middle of 2023 remains unchanged.If we are unable to resolve the deficiencies,we may need to amend the indications for use for which we are seeking authorization and / or conduct another clinical trial,and the authorization and commercial launch of BT- 001 could be significantly delayed or the authorization could be denied.** In addition,if granted marketing authorization,we ~~will~~ **may** be required to obtain additional FDA ~~approvals~~ **marketing authorizations** or clearances prior to ~~making~~ **marketing** certain ~~modification~~ **modifications** to our devices,and the FDA may revoke the ~~approval~~ **marketing authorization** or clearance or impose other restrictions if post- market data demonstrates safety issues or lack of efficacy.If we are unable to obtain and maintain the necessary regulatory authorizations and clearances to market our products,our financial condition may be adversely affected,and our ability to grow domestically and internationally would likely be limited.Additionally,even if authorized or cleared for marketing, ~~our~~ BT- 001 ~~digital therapeutic~~ may not receive marketing authorization for the indications that are necessary or desirable for successful commercialization or profitability.We are substantially dependent on the FDA' s de novo classification of ~~our~~ BT- 001 ~~digital therapeutic~~ ,as well as market acceptance in the United States of BT- 001,and our failure to receive FDA de novo classification of ~~our~~ BT- 001 ~~digital therapeutic~~ or the failure to gain such market acceptance for it would negatively impact our business.Since our inception,we have devoted substantially all of our efforts to the development of ~~our~~ BT- 001 ~~digital therapeutic~~ application that we believe,if granted de novo classification,will serve as the basis for future marketing clearances for additional uses in other indications. ~~We~~ **While we have a de novo classification request for BT- 001 pending with the FDA,we** have not yet received de novo classification from the FDA to market and sell ~~our~~ BT- 001 ~~digital therapeutic~~ in the United States **for any use** .However,we ~~will incur~~ **have begun incurring** costs,including costs to build our **commercial team and** sales force,in anticipation of potential FDA de novo classification being granted.If we are unable to obtain the necessary grant from the FDA to market and sell ~~our~~ BT- 001 ~~digital therapeutic~~ in the United States and then to achieve significant market acceptance in the United States,our results of operations will be adversely affected as the United States is expected to be the principal market for ~~our~~ BT- 001,if authorized.Further,because we have incurred costs prospectively in advance of FDA de novo classification,we would be unable to recoup these costs if the BT- 001 is not granted marketing authorization by the FDA or if it is granted de novo classification but fails to obtain market acceptance.We have other digital therapeutic candidates in development that depend on marketing clearance to be obtained under FDA' s 510 (k) clearance pathway,enabled by the de novo classification of our first BT- 001 product candidate;thus,if we are unsuccessful in obtaining de novo classification of our ~~initial~~ **pending de novo classification request for** BT- 001 ~~digital therapeutic~~ ,we would need to seek de novo classification for the next **digital therapeutic indication we seek to market.If de novo marketing authorization is granted for** BT- 001 ~~digital therapeutic indication we seek~~ **,it is uncertain whether,depending on their design and intended uses,future candidates may also be required by the FDA** to **obtain** ~~market~~ **marketing authorization through the de novo classification process,which would lead to longer more expensive development** .Unexpected or serious complications or other unforeseen negative effects related to the development or market acceptance of any **digital therapeutic we seek to market could materially and adversely affect our business.We completed a pivotal clinical trial and our de novo classification request for** BT- 001 ~~digital therapeutic we seek to market could materially and adversely affect our business.We are currently conducting a virtual clinical trial and plan to seek de novo classification for our BT- 001 digital therapeutic application~~ for the treatment of ~~type 2 diabetes~~ **T2D was accepted for substantive review by the FDA in October 2022** .The virtual aspects of the trial **design** ~~include~~ **included** recruitment of participants using email and social media and conducting the study using telemedicine visits.In order to obtain de novo classification,we must ~~obtain~~ **submit** clinical data demonstrating the safety and ~~efficacy~~ **effectiveness** of the product candidate.Conducting clinical trials is a complex and expensive process,can take many years,and outcomes are inherently uncertain. **For example,we announced results from our pivotal clinical trial of BT- 001 in July 2022,but the FDA will ultimately determine whether these results provide adequate support to grant our de novo classification request.** We **may** incur substantial expense for,and devote significant time to,clinical trials but cannot be certain that the trials will ever result in commercial revenue.We may experience significant setbacks in clinical trials,even after earlier clinical trials showed promising results,and failure can occur at any time during the clinical development process.Any of our products may malfunction or may produce undesirable adverse effects that could cause us,IRBs ~~,~~ or regulatory authorities to

interrupt,delay or halt clinical trials.We,IRBs,the FDA,or another regulatory authority may suspend or terminate clinical trials at any time to avoid exposing trial participants to unacceptable health risks. **In addition,** ~~Successful~~ **successful** results of earlier pilot studies are not necessarily indicative of future clinical trial results,and predecessor pilot study or clinical trial results may not be replicated in subsequent clinical trials.Moreover,interim results or topline results may be subject to change upon full review of the data from a clinical trial.Additionally,the FDA may disagree with our interpretation of the data from our pilot studies and clinical trials,or may find the clinical trial design,conduct or results inadequate to demonstrate safety or efficacy,and may require us to pursue additional clinical trials,which could further delay the de novo classification grant or clearance of our product candidates.The data we collect from our pilot studies and clinical trials may not be sufficient to support FDA de novo classification or clearance,and if we are unable to demonstrate the safety and efficacy of our future products in our clinical trials,we will be unable to obtain the regulatory authorizations we need to commercialize our products.In addition,we may estimate and publicly announce the anticipated timing of the accomplishment of various clinical,regulatory and other product development goals,which are often referred to as milestones.These milestones could include:the submission to the FDA of a meeting request to discuss product development pathways or submission **of an** IDE,if applicable,to commence clinical trials of our product candidates;the enrollment of patients in clinical trials;the release of data from clinical trials;the obtainment of the right to affix the CE mark in the European Union.The actual timing of these milestones could vary dramatically compared to our estimates,in some cases for reasons beyond our control.We cannot assure you that we will meet our projected milestones and if we do not meet these milestones as publicly announced,the commercialization of our products may be delayed and,as a result,our stock price may decline.Clinical trials are necessary to support de novo classification requests and certain 510 (k) **pre-** ~~premarket~~ --- **market** notifications and may be necessary to support subsequent 510 (k) submissions for modified versions of any digital therapeutic devices for which we obtain marketing authorization.This requires the enrollment of large numbers of suitable subjects,which may be difficult to identify,recruit and maintain as participants in the clinical trial.Adverse outcomes in our ~~potentially~~ pivotal trials or post- ~~approval~~ **market** studies could also result in restrictions on or withdrawal of marketing clearances we obtain.We will likely need to conduct additional clinical studies in the future for the authorization of the use of our products in some foreign countries.Clinical testing is difficult to design and implement,can take many years,can be expensive and carries uncertain outcomes.The initiation and completion of any of these trials may be prevented,delayed,or halted for numerous reasons.We may experience a number of events during the conduct of our clinical trials that could adversely affect the costs,timing or successful completion,including:• if we are required to submit an IDE application to FDA,which must become effective prior to commencing human clinical trials,the FDA may reject our IDE application and notify us that we may not begin investigational trials;• regulators and other comparable foreign regulatory authorities may disagree as to the design or implementation of our clinical trials;• regulators and / or IRBs,or other reviewing bodies may not authorize us or our investigators to commence a clinical trial,or to conduct or continue a clinical trial at a prospective or specific trial site;• we may not reach agreement on acceptable terms with prospective contract research organizations ~~,~~(" CROs") ~~,~~and clinical trial sites,the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;• we may have disagreements with CROs and clinical trial sites about the terms of our contracts with them and the amounts owed thereunder,and as a result,the costs of our clinical trials may be higher than anticipated;• clinical trials may produce negative or inconclusive results,or we may not agree with regulatory authorities on the interpretation of our clinical trial results,and we may decide,or regulators may require us,to conduct additional clinical trials or abandon product development programs;• the number of subjects or patients required for clinical trials,including to effectively test and demonstrate the effect of our product candidates,may be larger than we anticipate,enrollment in these clinical trials may be insufficient or slower than we anticipate,and the number of clinical trials being conducted at any given time may be high and result in fewer available patients for any given clinical trial,or patients may drop out of these clinical trials at a higher rate than we anticipate;• our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner,or at all;• we might have to suspend or terminate clinical trials for various reasons,including a finding that the subjects are being exposed to unacceptable health risks;• we may have to amend clinical trial protocols or conduct additional studies to reflect changes in regulatory requirements or guidance,which we may be required to submit to an IRB and / or regulatory authorities for re- examination;• regulators,IRBs,or other parties may require or recommend that we or our investigators suspend or terminate clinical research for various reasons,including safety signals or noncompliance with regulatory requirements;• the cost of clinical trials may be greater than we anticipate;• clinical sites may not adhere to the clinical protocol or may drop out of a clinical trial;• we may be unable to recruit a sufficient number of clinical trial sites or trial subjects;• regulators,IRBs,or other reviewing bodies may fail to approve or subsequently find fault with our manufacturing processes for clinical and commercial supplies,the supply of devices or other materials necessary to conduct clinical trials may be insufficient,inadequate or not available at an acceptable cost,or we may experience interruptions in our ability to supply our product candidates;• marketing authorization policies,pathways or regulations of FDA or applicable foreign regulatory agencies may change in a manner rendering our clinical data insufficient for marketing authorization;and • our current or future products may have undesirable side effects or other unexpected characteristics.Clinical trials must be conducted in accordance with the applicable laws and regulations of the FDA and other applicable regulatory authorities' ~~legal requirements,regulations or guidelines,and are subject to oversight by these governmental agencies and IRBs at the medical institutions where the clinical trials are conducted.We may in the future have to terminate a clinical trial site or investigator which is found through our clinical trial monitoring activities to be noncompliant with our clinical trial protocols or with applicable laws,regulations,requirements and guidelines for the conduct of our clinical trials.Furthermore,we rely on clinical trial sites to ensure the proper and timely conduct of our clinical trials and while we have agreements governing their committed activities,we have limited influence over their actual performance.We depend on our CROs to support the conduct of our clinical trials in compliance with good clinical practice (" GCP"),requirements.To the extent our CROs fail to help oversee the conduct the study in compliance with GCP standards or are~~

delayed for a significant time in the execution of the trial,including achieving full enrollment,we may be affected by increased costs,program delays or both.In addition,clinical trials that are conducted in countries outside the United States may subject us to further delays and expenses as a result of increased shipment costs,additional regulatory requirements and the engagement of non- U.S.CROs,as well as expose us to risks associated with clinical investigators who are unknown to the FDA,and different standards of diagnosis,screening and medical care.Failure can occur at any stage of clinical testing.Our clinical trials may produce negative or inconclusive results or may demonstrate a lack of effect of our product candidates.We may decide,or regulators may require us,to conduct additional clinical and non- clinical testing in addition to those we have planned.Our failure to adequately demonstrate the safety and effectiveness of any product candidates we may develop or may develop in the future would prevent receipt of regulatory marketing authorization and,ultimately,the commercialization of that product or indication for use.Even if our future products are granted de novo classification or cleared in the United States,commercialization of our products in foreign countries would require marketing authorization by regulatory authorities in those countries.Marketing authorization procedures vary among jurisdictions and can involve requirements and administrative review periods different from,and greater than,those in the United States,including the conduct of additional pilot studies or clinical trials.Any of these occurrences could have an adverse effect on our business,financial condition and results of operations.We may encounter delays or difficulties in enrolling,or be unable to enroll,a sufficient number of patients to complete any of our clinical trials on our current timelines,or at all,and even once enrolled,we may be unable to retain a sufficient number of patients to complete any of our trials.Slow enrollment in our clinical trials may lead to delays in our development timelines and milestones.Patient enrollment in clinical trials and completion of patient follow- up depend on many factors,including the size of the patient population,the nature of the trial protocol,the ability of patients to continue to receive medical care,the eligibility criteria for the clinical trial,patient compliance,competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the product being studied in relation to other available therapies,including any new treatments that may be approved for the indications we are investigating.For example,patients may be discouraged from enrolling in our clinical trials if the trial protocol requires them to undergo extensive post- treatment procedures or follow- up to assess the safety and efficacy of a product candidate,or they may be persuaded to participate in contemporaneous clinical trials of a competitor' s product candidate.In addition,patients participating in our clinical trials may drop out before completion of the trial or experience adverse medical events unrelated to our products.Delays in patient enrollment or failure of patients to continue to participate in a clinical trial may delay commencement or completion of the clinical trial,cause an increase in the costs of the clinical trial and delays,make our data more difficult to interpret,affect the powering of our trial,or result in the failure of the clinical trial.Delays or failures in planned patient enrollment or retention may result in increased costs,program delays or both,which could have a harmful effect on our ability to develop our product candidates,or could render further development impossible.In addition,we rely on clinical trial sites to ensure timely conduct of our clinical trials and,while we have entered into agreements governing their services,we are limited in our ability to compel their actual performance.Interim," topline," and preliminary data 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 confirmation,audit,and verification procedures that could result in material changes in the final data.From time to time,we may publicly disclose preliminary or topline data from our pilot studies and clinical trials,which is based on a preliminary analysis of then- available data,and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial.We also make assumptions,estimations,calculations,and conclusions as part of our analyses of data,and we may not have received or had the opportunity to fully and carefully evaluate all data.As a result,the topline or preliminary results that we report may differ from future results of the same studies,or different conclusions or considerations may qualify such results,once additional data have been received and fully evaluated.Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published.As a result,topline data should be viewed with caution until the final data are available.From time to time,we may also disclose interim data from our clinical trials.Interim or preliminary data from clinical trials are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment and treatment continues and more patient data become available or as patients from our clinical trials continue other treatments for their disease.Adverse differences between preliminary or interim data and final data could significantly harm our business prospects.Further,disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock.Further,others,including regulatory legal proceedings **requirements, regulations or guidelines,** and litigation **are subject** to oversight by these governmental agencies and IRBs at the medical institutions where the clinical trials are conducted.We may in the future have to terminate a clinical trial site or investigator which is found through our clinical trial monitoring activities to be noncompliant with our clinical trial protocols or with applicable laws,regulations,requirements and guidelines for the conduct of our clinical trials.Furthermore,we rely on clinical trial sites to ensure the proper and timely conduct of our clinical trials and while we have agreements governing their committed activities,we have limited influence over their actual performance.We depend on our CROs to support the conduct of our clinical trials in compliance with good clinical practice (" GCP") ,requirements.To the extent our CROs fail to help oversee the **and** conduct the study in compliance with GCP standards or are delayed for a significant time in the execution of the trial ,, including agreements governing their committed activities,we have limited influence over their actual performance.We depend on our CROs to support the conduct of our clinical trials in compliance with good clinical practice (" GCP"),requirements.To the extent our CROs fail to help oversee the conduct the study in compliance with GCP standards or are delayed for a significant time in the execution of the trial,including achieving full enrollment,we may be affected by increased costs,program delays or both.In addition,clinical trials that are conducted in countries outside the United States may subject us to further delays and expenses as a result of increased shipment costs,additional regulatory requirements and the engagement of non- U.S.CROs,as well as expose us to risks associated with clinical investigators who are unknown to the FDA,and different standards of

diagnosis,screening and medical care.Failure can occur at any stage of clinical testing.Our clinical trials may produce negative or inconclusive results or may demonstrate a lack of effect of our product candidates.We may decide,or regulators may require us,to conduct additional clinical and non- clinical testing in addition to those we have planned.Our failure to adequately demonstrate the safety and effectiveness of any product candidates we may develop or may develop in the future would prevent receipt of regulatory marketing authorization and,ultimately,the commercialization of that product or indication for use.Even if our future products are granted de novo classification or cleared in the United States,commercialization of our products in foreign countries would require marketing authorization by regulatory authorities in those countries.Marketing authorization procedures vary among jurisdictions and can involve requirements and administrative review periods different from,and greater than,those in the United States,including the conduct of additional pilot studies or clinical trials.Any of these occurrences could have an adverse effect on our business,financial condition and results of operations.We may encounter delays or difficulties in enrolling,or be unable to enroll,a sufficient number of patients to complete any of our clinical trials on our current timelines,or at all,and even once enrolled,we may be unable to retain a sufficient number of patients to complete any of our trials.Slow enrollment in our clinical trials may lead to delays in our development timelines and milestones.Patient enrollment in clinical trials and completion of patient follow- up depend on many factors,including the size of the patient population,the nature of the trial protocol,the ability of patients to continue to receive medical care,the eligibility criteria for the clinical trial,patient compliance,competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the product being studied in relation to other available therapies,including any new treatments that may be ~~approved~~ **authorized** for the indications we are investigating.For example,patients may be discouraged from enrolling in our clinical trials if the trial protocol requires them to undergo extensive post- treatment procedures or follow- up to assess the safety and efficacy of a product candidate,or they may be persuaded to participate in contemporaneous clinical trials of a competitor' s product candidate.In addition,patients participating in our clinical trials may drop out before completion of the trial or experience adverse medical events unrelated to our products.Delays in patient enrollment or failure of patients to continue to participate in a clinical trial may delay commencement or completion of the clinical trial,cause an increase in the costs of the clinical trial and delays,make our data more difficult to interpret,affect the powering of our trial,or result in the failure of the clinical trial.Delays or failures in planned patient enrollment or retention may result in increased costs,program delays or both,which could have a harmful effect on our ability to develop our product candidates,or could render further development impossible.In addition,we rely on clinical trial sites to ensure timely conduct of our clinical trials and,while we have entered into agreements governing their services,we are limited in our ability to compel their actual performance.Interim, ~~" "~~ topline, ~~" "~~ and preliminary data 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 confirmation,audit,and verification procedures that could result in material changes in the final data.From time to time,we may publicly disclose preliminary or topline data from our pilot studies and clinical trials,which is based on a preliminary analysis of then- available data,and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial.We also make assumptions,estimations,calculations,and conclusions as part of our analyses of data,and we may not have received or had the opportunity to fully and carefully evaluate all data.As a result,the topline or preliminary results that we report may differ from future results of the same studies,or different conclusions or considerations may qualify such results,once additional data have been received and fully evaluated.Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published.As a result,topline data should be viewed with caution until the final data are available.From time to time,we may also disclose interim data from our clinical trials.Interim or preliminary data from clinical trials are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment and treatment continues and more patient data become available or as patients from our clinical trials continue other treatments for their disease.Adverse differences between preliminary or interim data and final data could significantly harm our business prospects.Further,disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock.Further,others,including regulatory agencies,may not accept or agree with our assumptions,estimates,calculations,conclusions or analyses or may interpret or weigh the importance of data differently,which could impact the potential of the particular program,the likelihood of marketing authorization or clearance or commercialization of the particular product candidate,the commercial success of any product for which we may have already obtained authorization or clearance,and our company in general.In addition,the information we choose to publicly disclose regarding a particular study or clinical trial is derived from information that is typically extensive,and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure.If the interim,topline,or preliminary data that we report differ from actual results,or if others,including regulatory authorities,disagree with the conclusions reached,our ability to obtain ~~approval~~ **authorization** for,and commercialize,our product candidates may be harmed,which could harm our business,operating results,prospects or financial condition.Our ~~primary~~ **long- term growth depends on our ability to enhance our digital therapeutic products,expand our indications and develop and commercialize additional products once granted marketing authorization and clearance.It is important to our business** strategy **that we continue** to **enhance** ~~grow our revenue is to drive the adoption of our~~ BT- 001 ~~digital therapeutic~~ **with additional functionalities and** , ~~if granted marketing~~ **in the future,additional indications,as well as develop,seek** authorization ~~,by physicians to assist their patients in improving glycemic control by lowering HbA1c.Physicians may choose not to adopt our~~ - **or** ~~digital therapeutic~~ **clearance for and introduce new** products **.Developing products is expensive and time- consuming and could divert management' s attention away from our core business.The success of any new product offering** ~~for~~ - **or** ~~a number of reasons~~ **product enhancements will depend on several factors** ,including **our ability to** :• **properly identify and anticipate physician and patient needs** ~~lack of availability of adequate third- party payer coverage or reimbursement~~ ;• ~~lack of experience~~ **develop and introduce new functionalities,uses,products and product enhancements in a timely manner and in compliance** with ~~our product~~ **FDA regulations and expectations** ;• ~~our inability~~

avoid infringing upon the intellectual property **rights of third parties; • demonstrate, if required, the safety and effectiveness of new products with data from preclinical and pilot studies and clinical trials; • obtain the necessary regulatory clearances, authorizations or approvals for expanded indications, new products or product modifications; • be fully FDA- compliant with marketing of new products or modified products; • provide adequate training to potential patients prescribed our products; • receive adequate coverage and reimbursement for procedures performed with our products; and • develop ~~and~~ an ~~privacy disputes~~ effective and dedicated sales and marketing team. If we are not successful in expanding our indications and developing and commercializing new products and product enhancements, our ability to increase our revenue may be impaired** , which **could have a material adverse effect on our business, financial condition and results of operations. Our product candidates represent novel and innovative potential therapeutic areas, and negative perception of any product candidate that we develop could adversely affect our ability to conduct our business, obtain regulatory marketing authorization or identify alternate regulatory pathways to market for such product candidates. Certain of our product candidates** are ~~costly to~~ **considered relatively new and novel therapeutic approaches. Our and their success will ~~defend~~ depend upon physicians who specialize in the treatment of diseases targeted by our** and **their product candidates prescribing potential treatments that involve the use of our and their product candidates in lieu of, or in addition to, existing treatments with which they are more familiar and for which greater clinical data may be available. Access will also depend on consumer acceptance and adoption of products that are commercialized. In addition, responses by the U. S., state or foreign governments to negative public perception or ethical concerns may result in new legislation or regulations that** could ~~materially harm~~ **limit our ability to develop ~~our~~ or ~~business~~ commercialize any product candidates, obtain or maintain regulatory authorization, identify alternate regulatory pathways to market or otherwise achieve profitability. For example, in the United States, no prescription digital therapeutic candidates designed to deliver CBT for treating diabetes, heart disease,** and **other cardiometabolic conditions have been authorized to date. We are developing a platform of FDA- regulated, software- based, PDT candidates for treating such conditions through a novel form of CBT. The FDA may lack experience in evaluating the safety and effectiveness of product candidates based on CBT, which could ~~results~~ result in a longer than expected regulatory review process, increase expected development costs and delay or prevent potential commercialization** of ~~operations~~ **product candidates** . We may be party to lawsuits and legal proceedings in the normal course of business. These matters are often expensive and disruptive to normal business operations. We may face allegations, lawsuits and regulatory inquiries, audits and investigations regarding data privacy, security, labor and employment, consumer protection and intellectual property infringement, including claims related to privacy, patents, publicity, trademarks, copyrights and other rights. A portion of the technologies we use incorporates open source software, and we may face claims claiming ownership of open source software or patents related to that software, rights to our intellectual property or breach of open source license terms, including a demand to release material portions of our source code or otherwise seeking to enforce the terms of the applicable open source license. We may also face allegations or litigation related to our acquisitions, securities issuances or business practices, including public disclosures about our business. Litigation and regulatory proceedings, and particularly the patent infringement and class action matters we could face, may be protracted and expensive, and the results are difficult to predict. Certain of these matters may include speculative claims for substantial or indeterminate amounts of damages and include claims for injunctive relief. Additionally, our litigation costs could be significant. Adverse outcomes with respect to litigation or any of these legal proceedings may result in significant settlement costs or judgments, penalties and fines, or require us to modify our products or require us to stop offering certain products, all of which could negatively impact our revenue growth. We may also become subject to periodic audits, which would likely increase our regulatory compliance costs and may require us to change our business practices, which could negatively impact our revenue growth. Managing legal proceedings, litigation and audits, even if we achieve favorable outcomes, is time- consuming and diverts management' s attention from our business. The results of regulatory proceedings, litigation, claims, and audits cannot be predicted with certainty, and determining reserves for pending litigation and other legal, regulatory and audit matters requires significant judgment. There can be no assurance that our expectations will prove correct, and even if these matters are resolved in our favor or without significant cash settlements, these matters, and the time and resources necessary to litigate or resolve them, could harm our reputation, business, financial condition, results of operations and the market price of our common stock. Furthermore, our business exposes us to potential product liability claims if our products fail to properly perform due to undetected errors or similar problems. There can be no assurance that, despite testing we undertake, errors will not be found in new products after commencement of commercial use. In addition, the misuse of our products, or the failure of patients to adhere to operating guidelines, could cause significant harm to patients, including death, which could result in product liability claims. Product liability lawsuits and claims, with or without merit, could cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our core business, harm our reputation and adversely affect our ability to attract and retain patients, any of which could have a material adverse effect on our business, financial condition and results of operations. Although we maintain third- party product liability insurance coverage, it is possible that claims against us may exceed the coverage limits of our insurance policies. Even if any product liability loss is covered by an insurance policy, these policies typically have substantial deductibles for which we are responsible. Product liability claims in excess of applicable insurance coverage could have a material adverse effect on our business, financial condition and results of operations. In addition, any product liability claim brought against us, with or without merit, could result in an increase of our product liability insurance premiums. Insurance coverage varies in cost and can be difficult to obtain, and we cannot guarantee that we will be able to obtain insurance coverage in the future on terms acceptable to us or at all. We believe that our intellectual property is an essential asset of our business. If we do not adequately protect our intellectual property, our brand and reputation could be harmed and competitors may be able to use our technologies and erode or negate any competitive advantage we may have,

which could materially harm our business, negatively affect our position in the marketplace, limit our ability to commercialize our platform and delay or render impossible our achievement of profitability. A failure to protect our intellectual property in a cost- effective and meaningful manner could have a material adverse effect on our ability to compete. We regard the protection of our trade secrets, copyrights, trademarks, trade dress, databases, domain names and patents as critical to our success. We strive to protect our intellectual property rights by relying on federal, state and common law rights and other rights provided under foreign laws. These laws are subject to change at any time and could further restrict our ability to protect or enforce our intellectual property rights. In addition, the existing laws of certain foreign countries in which we operate may not protect our intellectual property rights to the same extent as do the laws of the United States. We also have a practice of entering into confidentiality and invention assignment agreements with our employees and contractors, and often enter into confidentiality agreements with parties with whom we conduct business in order to limit access to, and disclosure and use of, our proprietary information. In addition, from time to time we make our technology and other intellectual property available to others under license agreements, including open source license agreements and trademark licenses under agreements with any development collaborators for the purpose of co- branding or co- marketing our products or services. However, these contractual arrangements and the other steps we have taken to protect our intellectual property rights may not prevent the misappropriation of our proprietary information, infringement of our intellectual property rights, disclosure of trade secrets and other proprietary information, or deter independent development of similar or competing technologies, duplication of our technologies or efforts to design around our patents by others, and may not provide an adequate remedy in the event of such misappropriation or infringement. Obtaining and maintaining effective intellectual property rights is expensive, including the costs of defending our rights. We make business decisions about when to seek patent protection for a particular technology and when to rely upon trade secret protection, and the approach we select may ultimately prove to be inadequate. We are seeking to protect certain of our intellectual property rights through filing applications for copyrights, trademarks, patents and domain names in a number of jurisdictions, a process that is expensive and may not be successful in all jurisdictions. We are continuing to monitor and evaluate our intellectual property protection in various jurisdictions as we expand our business. Even in cases where we seek patent protection, there is no assurance that the resulting patents will effectively protect every significant feature of our products, technology, or proprietary information, or provide us with any competitive advantages. Moreover, we cannot guarantee that any of our pending patent applications will issue or be approved. The United States Patent and Trademark Office **("** ~~, or the~~ USPTO ~~,~~**")** also requires compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process and after a patent has **been** issued. There are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If this occurs, our competitors might be able to enter the market, which would have a material adverse effect on our business. Even where we have intellectual property rights, they may later be found to be unenforceable or have a limited scope of enforceability. In addition, we may not seek to pursue such protection in every jurisdiction. In particular, we believe it is important to maintain, protect and enhance our brands. Accordingly, we **may** pursue the registration of domain names and our trademarks and service marks in the United States and in some jurisdictions outside of the United States. Third parties may challenge our use of our trademarks, oppose our trademark applications or otherwise impede our efforts to protect our intellectual property in certain jurisdictions. In the event that we are unable to register our trademarks in certain jurisdictions, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. We have already and may, over time, increase our investment in protecting innovations through investments in patents and similar rights, and this process is expensive and time- consuming. In order to protect our intellectual property rights, we may be required to spend significant resources to monitor and protect these rights. We may not always detect infringement of our intellectual property rights, and defending or enforcing our intellectual property rights, even if successfully detected, prosecuted, enjoined or remedied, could result in the expenditure of significant financial and managerial resources. Litigation may be necessary to enforce our intellectual property rights, protect our proprietary rights or determine the validity and scope of proprietary rights claimed by others. Any litigation of this nature, regardless of outcome or merit, could result in substantial costs and diversion of management and technical resources, any of which could adversely affect our business and results of operations. We may also incur significant costs in enforcing our trademarks against those who attempt to imitate our brand and other valuable trademarks and service marks. Furthermore, our efforts to enforce our intellectual property rights may be met with defenses, counterclaims, countersuits and adversarial proceedings such as oppositions, inter partes review, post- grant review, re- examination or other post- issuance proceedings, that attack the validity and enforceability of our intellectual property rights. An adverse determination of any litigation proceedings could put our patents at risk of being invalidated or interpreted narrowly and could put our related pending patent applications at risk of not issuing. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential or sensitive information could be compromised by disclosure in the event of litigation. In addition, during the course of litigation there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. If we fail to maintain, protect and enhance our intellectual property rights, our business, results of operations and financial condition may be harmed and the market price of our common stock could decline. The process of seeking regulatory de novo..... candidates. Risks Related to Government Regulation We and our products are subject to extensive regulation in the United States and elsewhere, including by the FDA and its foreign counterparts. The FDA and foreign regulatory agencies regulate, among other things, with respect to medical devices: design, development and manufacturing; testing, labeling, content and language of instructions for use; clinical trials; product safety; **pre-** ~~premarket~~ ~~---~~ **market** clearance and approval; establishment registration and device listing; marketing, sales and distribution; complaint handling; record keeping procedures; advertising and promotion; recalls and field safety corrective actions; post- market

surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury; post- market approval studies; and product import and export. The regulations to which we are subject are complex and have tended to become more stringent over time. Regulatory changes could result in restrictions on our ability to carry on or expand our operations, higher than anticipated costs or lower than anticipated sales. The FDA enforces these regulatory requirements through periodic unannounced inspections. We do not know whether we will pass any future FDA inspections or those conducted by foreign regulatory agencies. Failure to comply with applicable regulations could jeopardize our ability to sell our products and result in enforcement actions such as: warning letters; fines; injunctions; civil penalties; termination of distribution; recalls or seizures of products; delays in the introduction of products into the market; total or partial suspension of production; refusal to grant future clearances or ~~approvals~~ **marketing authorizations** ; withdrawals or suspensions of current marketing authorizations, resulting in prohibitions on the sale and distribution of **any of** our **marketed** products; and in the most serious cases, criminal penalties. Our strategy is dependent on the initial de novo classification by **the** FDA of ~~our~~ BT- 001 ~~digital therapeutic~~ granting its ability for marketing in the United States. In the United States, before we can market a new medical device, or a new use of, new claim for or significant modification to an existing ~~products~~ **product** , we must first receive either clearance under Section 510 (k) of the FD & C Act, or ~~grant~~ **authorization** under the de novo classification process added under the FDAMA **, or pre- market approval** , or PMA, from the FDA, unless an exemption applies. The de novo classification process, which is the development pathway required based on discussions with the FDA for ~~our~~ BT- 001 ~~digital therapeutic~~ for our current planned use in treatment of **T2D** ~~type 2 diabetes~~ , provides a pathway to classify novel medical devices for which general controls alone, or general and special controls, provide reasonable assurance of safety and effectiveness for the intended use, but for which there is no legally marketed predicate device. A de novo classification is a risk- based classification process where devices that are classified into Class I or Class II through a de novo classification request may be marketed and used as predicates for future **pre-** ~~premarket~~ --- **market** notification 510 (k) submissions. In the 510 (k) clearance process, before a device may be marketed, the FDA must determine that a proposed device is ~~“~~ **"** substantially equivalent ~~”~~ **"** to a legally- marketed ~~“~~ **"** predicate ~~”~~ **"** device, which includes a device that has been previously cleared through the 510 (k) process, a device that was legally marketed prior to May 28, 1976 (pre- amendments device), a device that was originally on the United States market pursuant to an approved PMA and later down- classified, or a 510 (k)- exempt device. To be ~~“~~ **"** substantially equivalent, ~~”~~ **"** the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. Clinical data are sometimes required to support substantial equivalence demonstrations. We plan to pursue the 510 (k) clearance process for the addition of expanded indications for ~~our~~ BT- 001 ~~digital therapeutic~~ . Where the de novo classification or 510 (k) clearance pathways are not available for medical devices, and where no policy of enforcement discretion exists enabling a manufacturer to market a medical device without obtaining **pre-** ~~premarket~~ --- **market** authorization, the process of obtaining PMA approval may apply, which is the most rigorous product development pathway for seeking marketing approval for a medical device. In review of a PMA application, the FDA must determine that a proposed device is safe and effective for its intended use based, in part, on extensive data, including, but not limited to ~~pre- clinical~~ **preclinical** , clinical trial, technical, manufacturing and labeling data beyond that which is required to support a de novo classification request or 510 (k) clearance submission. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life- sustaining, life- supporting or implantable devices. Modifications to products that are approved through a PMA application generally require FDA approval. Similarly, certain modifications made to products cleared through a 510 (k) or the de novo classification process may require a new 510 (k) clearance or a new de novo classification request. **The** ~~Both the~~ PMA approval, de novo classification, and the 510 (k) clearance processes can be expensive, lengthy and uncertain. The FDA’ s 510 (k) clearance process usually takes from three to 12 months, but can last longer, while the de novo classification request process is usually longer and requires a clinical trial. The process of obtaining a PMA is much more costly and uncertain than the de novo or 510 (k) clearance processes and generally takes from one to three years, or even longer, from the time the application is filed with the FDA. In addition, a PMA generally requires the performance of one or more clinical trials. Despite the time, effort and cost, a device may not be approved, granted **marketing authorization** or cleared by the FDA. Any delay or failure to obtain necessary regulatory ~~approvals~~ **marketing authorizations** could harm our business. Furthermore, even if we are granted regulatory authorizations, clearances or approvals, they may include significant limitations on the indicated uses for the device, which may limit the market for the device. In the United States, we are currently developing ~~our~~ BT- 001 ~~digital therapeutic~~ through the de novo classification pathway. ~~Any~~ **Some** ~~modification~~ **modifications** to ~~our~~ BT- 001 ~~digital therapeutic~~ that ~~has~~ **have** not been previously authorized may require us to submit a 510 (k) **pre-** ~~premarket~~ --- **market** clearance application or **a subsequent** de novo classification request prior to implementing the change **for marketing** . If the FDA requires us to go through a lengthier, more rigorous examination for future products or modifications to existing products than we had expected, product introductions or modifications could be delayed or canceled, which could adversely affect our ability to grow our business. The FDA can delay, limit or deny de novo classification, clearance or approval of a device for many reasons, including: • our inability to demonstrate to the satisfaction of the FDA or the applicable regulatory entity or notified body that our products are safe or effective for their intended uses; • the disagreement of the FDA or the applicable foreign regulatory body with the design or implementation of our clinical trials or the interpretation of data from ~~pre- clinical~~ **preclinical** studies or clinical trials; • serious and unexpected adverse device effects experienced by participants in our clinical trials; • the data from our ~~pre- clinical~~ **preclinical** or pilot studies and clinical trials may be insufficient to support de novo classification, clearance or approval where required; • our inability to demonstrate that the clinical and other benefits of the device outweigh the risks; and • the potential for medical device policies or regulations of the FDA or applicable foreign regulatory bodies to change significantly in a manner rendering our clinical data or regulatory filings insufficient for de novo classification, clearance or approval. In addition, the FDA may change its policies, adopt

additional regulations or revise existing regulations, or take other actions, which may prevent or delay de novo classification, clearance or approval of our future products under development or impact our ability to modify our currently cleared products on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain new authorizations, increase the costs of compliance or restrict our ability to maintain any authorizations we may successfully obtain. We may market digital products for uses under current FDA enforcement discretion or outside of the current definition of a ~~“~~ **"** medical device ~~”~~ **"** in the United States. Currently, the FDA' s regulatory framework permits the marketing of certain digital applications and products outside of the FDA' s active regulation under its device authorities or, in other cases, completely outside FDA regulation if the product uses do not meet the definition of a ~~“~~ **"** medical device. ~~”~~ **"** From time to time, we may develop and commercialize products that we determine fall within the current areas of FDA enforcement discretion or outside the definition of a medical device, but the FDA may not agree with our determination. If the FDA disagrees with any such determinations that we make, we may be required to cease further marketing or distribution of those products until such time as we obtain any required **pre-** ~~premarket~~ --- **market** authorization, clearance or approval for those products and we may be subject to receiving an FDA untitled letter or warning letter for such product marketing and distribution activities, amongst other potential enforcement mechanisms available to the FDA. Failure to comply with post- marketing regulatory requirements could subject us to enforcement actions, including substantial penalties, and might require us to recall or withdraw ~~a~~ products from the market. After de novo classification, if granted, for ~~our~~ BT- 001 ~~digital therapeutic product candidate~~, we will be subject to ongoing and pervasive regulatory requirements governing, among other things, the manufacture, marketing, labeling, sale, promotion, advertising, medical device reporting, registration, distribution, and listing of devices. For example, we must submit reports to the FDA, for certain adverse events. Failure to submit such reports, or failure to submit the reports in a timely manner, could result in enforcement action by the FDA. Following its review of these medical device adverse event reports, the FDA might ask for additional information or initiate further investigation. In addition, our digital therapeutics may become subject to post- market study requirements. Any failure to conduct the required studies in accordance with an IRB, and informed consent requirements, or adverse findings in these studies, could also be grounds for modification or withdrawal of marketing authorization for any product we may commercialize. The FDA and the FTC, also regulate the advertising and promotion of our products and services to ensure that the claims we make are consistent with our regulatory authorizations, that there is adequate and reasonable data to substantiate the claims and that our promotional labeling and advertising is neither false nor misleading. If the FDA or 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 warning letters, and we may be required to revise our promotional claims and make other corrections or restitutions. The regulations to which we are subject are complex and have become more stringent over time. Regulatory changes could result in restrictions on our ability to continue or expand our operations, higher than anticipated costs, or lower than anticipated sales. Even after we have obtained the proper regulatory authorization to market a device, we have ongoing responsibilities under FDA regulations and applicable foreign laws and regulations. The FDA, state and foreign regulatory authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA, state or foreign regulatory authorities, which may include any of the following sanctions: • untitled letters or warning letters; • fines, injunctions, consent decrees and civil penalties; • recalls, termination of distribution, administrative detention, or seizure of our products; • patient notifications for repair, replacement or refunds; • operating restrictions or partial suspension or total shutdown of production; • delays in or refusal to grant our requests for future marketing authorizations of new products, new intended uses, or modifications to any marketed products we may commercialize; • withdrawals or suspensions of our regulatory authorizations, resulting in prohibitions on sales and distribution of our products; • FDA refusal to issue certificates to foreign governments needed to export products for sale in other countries; and • criminal prosecution. Any of these sanctions could result in higher than anticipated costs or lower than anticipated sales and have a material adverse effect on our reputation, business, financial condition and results of operations. If treatment guidelines for diabetes patient management change or the standard of care evolves, we may need to redesign and seek new marketing authorization from the FDA for one or more of our product candidates. If treatment guidelines for diabetes patient management change or the standard of care for this or any other conditions in which we seek to develop digital therapeutics evolves, we may need to redesign the applicable product or product candidates we market or seek to develop and may need to seek and obtain new de novo classifications, clearances or approvals from the FDA and the equivalent from foreign regulatory authorities. If treatment guidelines or the standards of care change so that different treatments become desirable, the clinical utility of one or more of our products could be diminished and our business could be adversely affected. The misuse or off- label use of our products may harm our reputation in the marketplace, result in injuries that lead to product liability suits or result in costly investigations, fines or sanctions by regulatory bodies if we are deemed to have engaged in the promotion of these uses, any of which could be costly to our business. Although our products, if authorized for marketing, are marketed for the specific therapeutic uses for which the devices were designed and our personnel will be trained to not promote our products for uses outside of the FDA- approved indications for use, known as ~~“~~ **"** off- label uses, ~~”~~ **"** we cannot, however, prevent a physician from using our products in ways, when in the physician' s independent professional medical judgment, he or she deems it appropriate. There may be increased risk of injury to patients if primary care physicians attempt to use our products off- label. Furthermore, the use of our products for indications other than those authorized, cleared or approved by the FDA or authorized by any foreign regulatory body may not effectively treat such conditions, which could harm our reputation in the marketplace among primary care physicians and patients. If following authorization of ~~our~~ BT- 001 ~~digital therapeutic~~ or any other product candidates we may commercialize the FDA or any foreign regulatory body determines that our promotional materials or training ~~constitute~~ **include** promotion of an off- label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance or imposition of an untitled letter or warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible

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

business may rely, which could negatively impact our business. The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, the ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and / or approved by necessary government agencies, which would adversely affect our business. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations. In the United States and markets in other countries, patients generally rely on third- party payers to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payers is critical to new product acceptance. Our ability to successfully commercialize our product candidates will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations **and whether we are successful in obtaining coverage from a broad spectrum of payers** . Government authorities and other third- party payers, such as private health insurers and health maintenance organizations, decide which products they will pay for and establish reimbursement levels. In the United States, the principal decisions about reimbursement for new products are typically made by CMS, an agency within the **HHS** ~~U. S. Department of Health and Human Services~~ . CMS decides whether and to what extent a new ~~medicine~~ **product** will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. The availability of coverage and extent of reimbursement by governmental and private payers is essential for most patients to be able to afford treatments. Sales of product candidates that we may identify will depend substantially, both domestically and abroad, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third- party payers. If coverage and adequate reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment. **Further, if we are not successful in obtaining coverage from a broad spectrum of payers, our ability to successfully commercialize our product candidates may be impacted.** There is also significant uncertainty related to the insurance coverage and reimbursement of newly **authorized, cleared, or** approved products and coverage may be more limited than the purposes for which the ~~medicine~~ **product** is ~~approved~~ **authorized for marketing** by the FDA or comparable foreign regulatory authorities. Factors payers consider in determining reimbursement are based on whether the product is: • a covered benefit under its health plan; • safe, effective and medically necessary; • appropriate for the specific patient; • cost- effective; and • neither experimental nor investigational. Each payer determines whether ~~or not~~ it will provide coverage for a treatment, **under what benefit (pharmacy, medical, other),** what amount it will pay the manufacturer for the treatment **,** and on what tier of its **pharmacy** formulary **or under what medical coverage policy** it will be placed. The position on a payer' s list of covered drugs, biological products, and medical devices, or formulary, generally determines the co- payment that a patient will need to make to obtain the therapy and can strongly influence the adoption of such therapy by patients and physicians. Patients who are prescribed treatments for their conditions and providers prescribing such services generally rely on third- party payers to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products. There may be significant delays in obtaining such coverage and reimbursement for newly ~~approved~~ **marketed** products, and coverage may be more limited than the purposes for which the product is ~~approved~~ **authorized for marketing** by the FDA. Moreover, eligibility for coverage and reimbursement does not imply that a product will be paid for in all cases or at a rate that covers our costs, including research, development, intellectual property, manufacture, sale and distribution expenses. Interim reimbursement levels for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the product and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost products and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private payers, by any future laws limiting product prices. Third- party payers have attempted to control costs by limiting coverage and the amount of reimbursement for particular products. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Inadequate coverage and reimbursement may impact the demand for, or the price of, any product for which we obtain marketing ~~approval~~ **authorization** . If coverage and adequate reimbursement are not available, or are available only at limited levels, we may not be able to successfully commercialize our product candidates. In addition, in some foreign countries, the proposed pricing for a prescription device must be approved before it may be lawfully marketed. The requirements governing product pricing vary widely from country to country. For example, the European Union provides options for its Member States to restrict the range of products for which their national health insurance systems provide reimbursement and to control the prices of products for human use. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product to currently available therapies. A Member State may approve a specific price for the products or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. There

can be no assurance that any country that has price controls or reimbursement limitations for products will allow favorable reimbursement and pricing arrangements for any of our product candidates. Historically, products launched in the European Union do not follow price structures of the U. S. and generally prices tend to be significantly lower. We **may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws health information privacy and security laws, and other health care laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties. We** are subject to applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the U. S. federal Anti- Kickback Statute and the FCA, which may constrain the business or financial arrangements and relationships through which we sell, market and distribute our products. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry (e. g., healthcare providers, physicians and third- party payers), are subject to extensive laws designed to prevent fraud, kickbacks, self- dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission (s), certain customer incentive programs and other business arrangements generally. We also may be subject to patient information and privacy and security regulation by both the federal government and the states and foreign jurisdictions in which we conduct our business. The applicable federal, state and foreign healthcare laws and regulations laws that may affect our ability to operate include, but are not limited to: • the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, the purchase, lease, order, arrangement, or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the federal Anti- Kickback Statute or specific intent to violate it to have committed a violation. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA or federal civil money penalties ~~.~~ **;** • the federal civil and criminal false claims laws and civil monetary penalty laws, such as the FCA, which impose criminal and civil penalties and authorize civil whistleblower or qui tam actions, against individuals or entities for, among other things: knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent; knowingly making, using or causing to be made or used, a false statement of record material to a false or fraudulent claim or obligation to pay or transmit money or property to the federal government or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the federal government. A person can be held liable under the FCA even when they do not submit claims directly to government payers if they are deemed to ~~“~~ **"** cause ~~”~~ **"** the submission of false or fraudulent claims. The FCA also permits a private individual acting as a ~~“~~ **"** whistleblower ~~”~~ **"** to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery; • HIPAA, which created new federal criminal statutes that prohibit a person from knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payer (e. g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false, fictitious, or fraudulent statements or representations in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters; similar to the federal Anti- Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation; • HIPAA, as amended by HITECH and their respective implementing regulations, including the Final Omnibus Rule published in January 2013, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates, independent contractors or agents of covered entities, that perform services for them that involve the creation, maintenance, receipt, use, or disclosure of, individually identifiable health information relating to the privacy, security and transmission of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, there may be additional federal, state and non- U. S. laws which govern the privacy and security of health and other personal information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts; • The U. S. federal transparency requirements under the ACA, including the provision commonly referred to as the Physician Payments Sunshine Act, and its implementing regulations, which requires applicable manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children' s Health Insurance Program to report annually to CMS, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) **, certain other licensed health care practitioners** and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members ~~. Effective January 1, 2022, these reporting obligations extend to include transfers of value made to certain non- physician providers such as physician assistants and nurse practitioners~~ ; • federal government price reporting laws, which require us to calculate and report complex pricing metrics in an accurate and timely manner to government programs; **and** • federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers **.** ~~; and •~~ Additionally, we are subject to state and foreign equivalents of each of the healthcare laws and regulations described above, among others, some of which may be broader in scope and may apply regardless of the payer. Many U. S. states have adopted laws similar to the federal Anti- Kickback Statute

and the FCA, and may apply to our business practices, including, but not limited to, research, distribution, sales or marketing arrangements and claims involving healthcare items or services reimbursed by non- governmental payers, including private insurers. Several states also impose other marketing restrictions or require medical device manufacturers to make marketing or price disclosures to the state. State and foreign laws, including for example the European Union General Data Protection Regulation, which became effective May 2018 also govern 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. There are ambiguities as to what is required to comply with these state requirements and if we fail to comply with an applicable state law requirement we could be subject to penalties. Finally, there are state and foreign laws governing the privacy and security of health information, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge and may not comply under one or more of such laws, regulations, and guidance. Law enforcement authorities are increasingly focused on enforcing fraud and abuse laws, and it is possible that some of our practices may be challenged under these laws. Efforts to ensure that our current and future business arrangements with third parties, and our business generally, will comply with applicable healthcare laws and regulations will involve substantial costs. If our operations, including our arrangements with physicians and other healthcare providers are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to penalties, including, without limitation, administrative, civil and criminal penalties, damages, fines, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs (such as Medicare and Medicaid), and imprisonment, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non- compliance with these laws, any of which could adversely affect our ability to operate our business and our financial results. We are subject to data privacy and security laws and regulations governing our collection, use, disclosure, or storage of personally identifiable information, including protected health information and payment card data, which may impose restrictions on us and our operations and subject us to penalties if we are unable to fully comply with such laws. Numerous federal and state laws and regulations govern the collection, use, disclosure, storage and transmission of personally identifiable information, including protected health information. These laws and regulations, including their interpretation by governmental agencies, are subject to frequent change and could have a negative impact on our business. In addition, in the future, industry requirements or guidance, contractual obligations, and / or legislation at both the federal and the state level may limit, forbid or regulate the use or transmission of health information outside of the United States. These varying interpretations can create complex compliance issues for us and our partners and potentially expose us to additional expense, adverse publicity and liability, any of which could adversely affect our business. Federal and state consumer protection laws are increasingly being applied by the FTC, and states' attorneys general to regulate the collection, use, storage and disclosure of personal or personally identifiable information, through websites or otherwise, and to regulate the presentation of website content. The security measures that we and our third- party vendors and subcontractors have in place to ensure compliance with privacy and data protection laws may not protect our facilities and systems from security breaches, acts of vandalism or theft, computer viruses, misplaced or lost data, programming and human errors or other similar events. Even though we provide for appropriate protections through our agreements with our third party vendors, we still have limited control over their actions and practices. A breach of privacy or security of personally identifiable health information may result in an enforcement action, including criminal and civil liability, against us. We are not able to predict the extent of the impact such incidents may have on our business. Enforcement actions against us could be costly and could interrupt regular operations, which may adversely affect our business. While we have not received any notices of violation of the applicable privacy and data protection laws and believe we are in compliance with such laws, there can be no assurance that we will not receive such notices in the future. There is ongoing concern from privacy advocates, regulators and others regarding data privacy and security issues, and the number of jurisdictions with data privacy and security laws has been increasing. Also, there are ongoing public policy discussions regarding whether the standards for de- identification, anonymization or pseudonymization of health information are sufficient, and the risk of re- identification sufficiently small, to adequately protect patient privacy. We expect that there will continue to be new proposed and amended laws, regulations and industry standards concerning privacy, data protection and information security in the United States, such as the CCPA. Further, the CPRA was passed by California voters on November 3, 2020. The CPRA will create additional obligations with respect to processing and storing personal information that are scheduled to take effect on January 1, 2023 (with certain provisions having retroactive effect to January 1, 2022). Other U. S. states also are considering omnibus privacy legislation and industry organizations regularly adopt and advocate for new standards in these areas. While the CCPA and CPRA contains ~~an~~ exceptions for certain activities involving PHI under HIPAA, we cannot yet determine the impact the CCPA, CPRA or other such future laws, regulations and standards may have on our business. Future laws, regulations, standards, obligations amendments, and changes in the interpretation of existing laws, regulations, standards and obligations could impair our or our clients' ability to collect, use or disclose information relating to patients or consumers, including information derived therefrom, which could decrease demand for our Platform, increase our costs and impair our ability to maintain and grow our client base and increase our revenue. Accordingly, we may find it necessary or desirable to fundamentally change our business activities and practices or to expend significant resources to modify our software or platform and otherwise adapt to these changes. Further, our patients may expect us to comply with more stringent privacy and data security requirements than those imposed by laws, regulations or self- regulatory requirements, and we may be obligated contractually to comply with additional or different standards relating to our handling or protection of data. Any failure or perceived failure by us to comply with federal or state laws or regulations, industry standards or other legal obligations, or any actual or suspected privacy or security incident, whether or not resulting in unauthorized access to, or

acquisition, release or transfer of personally identifiable information or other data, may result in governmental enforcement actions and prosecutions, private litigation, fines and penalties or adverse publicity and could cause our clients to lose trust in us, which could have an adverse effect on our reputation and business. We may be unable to make such changes and modifications in a commercially reasonable manner or at all, and our ability to develop new products could be limited. Any of these developments could harm our business, financial condition and results of operations. Privacy and data security concerns, whether valid or not valid, may inhibit retention of our Platform by existing clients or adoption of our Platform by new clients. Healthcare legislative reform measures and constraints on national budget social security systems may have a material adverse effect on our business and results of operations. In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the health care system that could impact our ability to sell our products profitably. In particular, in 2010, the ACA, was enacted, which, among other things, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program; extended the Medicaid Drug Rebate program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations; subjected manufacturers to new annual fees and taxes for certain branded prescription drugs; created a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50 % (increased to 70 % pursuant to the Bipartisan Budget Act of 2018, effective as of January 1, 2019) point- of- sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer' s outpatient drugs to be covered under Medicare Part D; and provided incentives to programs that increase the federal government' s comparative effectiveness research. Since its enactment, there have been judicial, Congressional and executive challenges to certain aspects of the ACA. On June 17, 2021, the U. S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court' s decision, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how other healthcare reform measures of the Biden administration or other efforts, if any, to challenge, repeal or replace the ACA will impact our business. Other legislative changes have been proposed and adopted in the United States since the **ACA** ~~Affordable Care Act~~ was enacted. **The** ~~In August 2011, the~~ Budget Control Act of 2011 **and subsequent legislation** , among other things, created measures for spending reductions **that resulted in** ~~by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $ 1. 2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation' s automatic reduction to several government programs. This includes~~ aggregate reductions of Medicare payments to providers up to 2 % per fiscal year, ~~and~~ **which** , due to subsequent legislative amendments, will remain in effect through 2030 unless additional Congressional action is taken. **In August 2022** ~~Pursuant to the Coronavirus Aid~~ , **the Inflation Reduction** ~~Relief, and Economic Security~~ Act **of 2022 (the" IRA") was signed into law. The IRA includes several provisions that may impact our business** , ~~also~~ **depending on how various aspects of the IRA are implemented. Provisions that may impact our business include a $ 2, 000 out- of- pocket cap for Medicare Part D beneficiaries, the imposition of new manufacturer financial liability on all drugs in Medicare Part D, permitting the U. S. government to negotiate Medicare Part B and Part D pricing for certain high- cost drugs and biologics without generic or biosimilar competition, requiring companies to pay rebates to Medicare for drug prices that increase faster than inflation, and delaying the rebate rule that would require pass through of pharmacy benefit manager rebates to beneficiaries. The effect of IRA on our business and the healthcare industry in general is not yet** known ~~as the CARES Act, as well as subsequent legislation, these reductions have been suspended from May 1, 2020 through March 31, 2022 due to the ongoing COVID- 19 pandemic. Following the temporary suspension, a 1 % payment reduction will occur beginning April 1, 2022 through June 30, 2022, and the 2 % payment reduction will resume on July 1, 2022~~ . There has been increasing legislative and enforcement interest in the United States with respect to product pricing practices. Specifically, there have been several recent U. S. Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to product pricing, reduce the cost of products under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. The HHS has already started the process of soliciting feedback on some of these measures and, at the same time, is immediately implementing others under its existing authority. It is unclear what effect such legislative and enforcement interest may have on prescription devices. We expect that these and other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any ~~approved~~ **marketed** device, which could have an adverse effect on patients for our product candidates. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payers. There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels in the U. S. directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products. Such reforms could have an adverse effect on anticipated revenue from products that we may successfully develop and for which we may obtain regulatory ~~approval~~ **marketing authorization** and may affect our overall financial condition and ability to develop product candidates. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our current or any future product candidates we may develop may lose any regulatory

~~approval~~ **marketing authorization** that may have been obtained and we may not achieve or sustain profitability. Our employees, independent contractors, consultants, commercial collaborators, principal investigators, vendors and other agents may engage in misconduct or other improper activities, including non- compliance with regulatory standards and requirements. We are exposed to the risk that our employees, independent contractors, consultants, commercial collaborators, principal investigators, vendors and other agents may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless or negligent conduct or disclosure of unauthorized activities to us that violates applicable regulations, including those laws requiring the reporting of true, complete and accurate information to regulatory agencies, manufacturing standards and U. S. federal and state healthcare laws and regulations. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. We could face liability under the U. S. federal Anti- Kickback Statute and similar U. S. state laws. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, referrals, customer incentive programs and other business arrangements. Misconduct by these parties could also involve the improper use of individually identifiable information, including, without limitation, information obtained in the course of clinical trials, which could result in significant regulatory sanctions and serious harm to our reputation. Further, should violations include promotion of unapproved (off- label) uses one or more of our products, we could face significant regulatory sanctions for unlawful promotion, as well as substantial penalties under the FCA, and similar state laws. Similar concerns could exist in jurisdictions outside of the United States as well. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. The precautions we take to detect and prevent misconduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of noncompliance with these laws, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business, financial condition and results of operations. Risks Related to Our Legal and Regulatory Environment We are subject to the U. S. Foreign Corrupt Practices Act (the" FCPA") and other anti- corruption, anti- bribery, and anti- money laundering laws in the jurisdictions in which we do business, both domestic and abroad. These laws generally prohibit us and our employees from improperly influencing government officials or commercial parties in order to obtain or retain business, direct business to any person or gain any improper advantage. The FCPA and similar applicable anti- bribery and anti- corruption laws also prohibit our third- party business partners, representatives and agents from engaging in corruption and bribery. We and our third- party business partners, representatives and agents may have direct or indirect interactions with officials and employees of government agencies or state- owned or affiliated entities. We may be held liable for the corrupt or other illegal activities of these third- party business partners and intermediaries, our employees, representatives, contractors, partners and agents, even if we do not explicitly authorize such activities. These laws also require that we keep accurate books and records and maintain internal controls and compliance procedures designed to prevent any such actions. While we have policies and procedures to address compliance with such laws, we cannot assure you that our employees and agents will not take actions in violation of our policies or applicable law, for which we may be ultimately held responsible. Our exposure for violating these laws will increase as we expand internationally and as we commence sales and operations in foreign jurisdictions. Any violation of the FCPA or other applicable anti- bribery, anti- corruption laws and anti- money laundering laws could result in whistleblower complaints, adverse media coverage, investigations, imposition of significant legal fees, loss of export privileges, severe criminal or civil sanctions or suspension or debarment from U. S. government contracts, substantial diversion of management' s attention, drop in stock price or overall adverse consequences to our business, all of which may have an adverse effect on our reputation, business, financial condition, and results of operations. Our operations are subject to a variety of federal, state and local employment-related laws and regulations, including, but not limited to, the U. S. Fair Labor Standards Act, which governs such matters as minimum wages, the Family Medical Leave Act, overtime pay, compensable time, recordkeeping and other working conditions, Title VII of the Civil Rights Act, the Employee Retirement Income Security Act, the Americans with Disabilities Act, the National Labor Relations Act, regulations of the Equal Employment Opportunity Commission, regulations of the Office of Civil Rights, regulations of the Department of Labor (DOL), regulations of state attorneys general, federal and state wage and hour laws, and a variety of similar laws enacted by the federal and state governments that govern these and other employment- related matters. As our employees are located in a number of states, compliance with these evolving federal, state and local laws and regulations could substantially increase our cost of doing business while failure to do so could subject us to fines and lawsuits. We are currently subject to employee- related legal proceedings in the ordinary course of business. While we believe that we have adequate reserves for those losses that we believe are probable and can be reasonably estimated, the ultimate results of legal proceedings and claims cannot be predicted with certainty. ~~Management' s focus and resources may be diverted from operational matters and other strategic opportunities as a result of the recently completed Business Combination. The Business Combination may place a significant burden on our management and other internal resources. The diversion of management' s attention and any difficulties encountered in the transition process could harm our financial condition, results of operations and prospects. In addition, uncertainty about the effect of the Business Combination on our systems, employees, customers, partners, and other third parties, including regulators, may have an adverse effect on us. These uncertainties may impair our ability to~~

attract, retain and motivate key personnel for a period of time after the completion of the Business Combination. We will incur significant increased expenses and administrative burdens as a public company, which could have an adverse effect on our business, financial condition and results of operations. As a public company, we will face increased legal, accounting, administrative and other costs and expenses as a public company that we did not incur as a private company. The Sarbanes-Oxley Act, including the requirements of Section 404, as well as rules and regulations subsequently implemented by the SEC, the Dodd- Frank Wall Street Reform and Consumer Protection Act of 2010 and the rules and regulations promulgated and to be promulgated thereunder, the (" PCAOB") and the securities exchanges, impose additional reporting and other obligations on public companies. Compliance with public company requirements will increase costs and make certain activities more time-consuming. A number of those requirements will require us to carry out activities we have not done previously. In addition, additional expenses associated with SEC reporting requirements will be incurred. Furthermore, if any issues in complying with those requirements are identified (for example, if the auditors identify a material weakness or significant deficiency in the internal control over financial reporting), we could incur additional costs rectifying those issues, and the existence of those issues could adversely affect our reputation or investor perceptions of it. It may also be more expensive to obtain director and officer liability insurance. Risks associated with our status as a public company may make it more difficult to attract and retain qualified persons to serve on our Board or as executive officers. The additional reporting and other obligations imposed by these rules and regulations will increase legal and financial compliance costs and the costs of related legal, accounting and administrative activities. These increased costs will require us to divert a significant amount of money that could otherwise be used to expand the business and achieve strategic objectives. Advocacy efforts by stockholders and third parties may also prompt additional changes in governance and reporting requirements, which could further increase costs. We qualify as an " emerging growth company " and as a " smaller reporting company ", and if we take advantage of certain exemptions from disclosure requirements available to emerging growth companies or smaller reporting companies, which could make our securities less attractive to investors and may make it more difficult to compare our performance to the performance of other public companies. We qualify as an " emerging growth company " as defined in Section 2 (a) (19) of the Securities Act, as modified by the JOBS Act. As such, we are eligible for and intend to take advantage of certain exemptions from various reporting requirements applicable to other public companies that are not emerging growth companies for as long as we continue to be an emerging growth company, including (i) the exemption from the auditor attestation requirements with respect to internal control over financial reporting under Section 404 (b) of the Sarbanes- Oxley Act, (ii) the exemptions from say- on- pay, say-on- frequency and say- on- golden parachute voting requirements and (iii) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We will remain an emerging growth company until the earliest of (i) the last day of the fiscal year in which the market value of the shares of our common stock that are held by non- affiliates exceeds $ 700 million as of June 30 of that fiscal year, (ii) the last day of the fiscal year in which we have total annual gross revenue of $ 1. 07 billion or more during such fiscal year, (iii) the date on which we have issued more than $ 1 billion in non-convertible debt in the prior three- year period or (iv) the last day of the fiscal year following the fifth anniversary of the date of the first sale of our common stocks in our IPO. In addition, Section 107 of the JOBS Act also provides that an emerging growth company can take advantage of the exemption from complying with new or revised accounting standards provided in Section 7 (a) (2) (B) of the Securities Act as long as we are an emerging growth company. An emerging growth company can therefore delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption from new or revised accounting standards and, therefore, we may not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. Investors may find our common stock less attractive because we will rely on these exemptions, which may result in a less active trading market for our common stock and its stock price may be more volatile. We are also a " smaller reporting company, " meaning that the market value of our stock held by non- affiliates is less than $ 700 million as of the prior June 30 and our annual revenue is less than $ 100 million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market value of our stock held by non- affiliates is less than $ 250 million as of the prior June 30 or (ii) our annual revenue is less than $ 100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $ 700 million as of the prior June 30. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in this Annual Report and take advantage of reduced disclosure obligations regarding executive compensation. If we fail to maintain an effective system of disclosure controls and internal control over financial reporting, our ability to produce timely and accurate financial statements or comply with applicable regulations could be impaired. As a public company, we are subject to the reporting requirements of the Exchange Act, the Sarbanes- Oxley Act **of 2002 (the" Sarbanes- Oxley Act")** and the rules and regulations of the applicable listing standards of The Nasdaq Capital Market (" Nasdaq") . We expect that the requirements of these rules and regulations will continue to increase our legal, accounting and financial compliance costs, make some activities more difficult, time- consuming and costly and place significant strain on our personnel, systems and resources. The Sarbanes- Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We are continuing to develop and refine our disclosure controls and other procedures that are designed to ensure that information required to be disclosed by us in the reports that we will file with the SEC is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms and that information required to be disclosed in reports under the Exchange Act is accumulated and communicated to our principal executive and financial officers. We are also continuing to improve our internal control over financial reporting, which includes hiring additional accounting and financial personnel to implement such processes and controls. In order to maintain and improve the effectiveness of our disclosure controls and procedures and internal control over

financial reporting, we have expended, and anticipate that we will continue to expend, significant resources, including accounting- related costs and significant management oversight. If any of these new or improved controls and systems do not perform as expected, we may experience material weaknesses in our controls. Our current controls and any new controls that we develop may become inadequate because of changes in conditions in our business. Further, weaknesses in our disclosure controls and internal control over financial reporting may be discovered in the future. Any failure to develop or maintain effective controls or any difficulties encountered in their implementation or improvement could harm our results of operations or cause us to fail to meet our reporting obligations and may result in a restatement of our financial statements for prior periods. Any failure to implement and maintain effective internal control over financial reporting also could adversely affect the results of periodic management evaluations and annual independent registered public accounting firm attestation reports regarding the effectiveness of our internal control over financial reporting that we will eventually be required to include in our periodic reports that will be filed with the SEC. Ineffective disclosure controls and procedures and internal control over financial reporting could also cause investors to lose confidence in our reported financial and other information, which would likely have a negative effect on the trading price of our common stock. In addition, if we are unable to continue to meet these requirements, we may not be able to remain listed on Nasdaq. We are not currently required to comply with the SEC rules that implement Section 404 of the Sarbanes- Oxley Act and are therefore not required to make a formal assessment of the effectiveness of our internal control over financial reporting for that purpose. As a public company, we are required to provide an annual management report on the effectiveness of our internal control over financial reporting commencing with our second annual report on Form 10- K. Our independent registered public accounting firm is not required to formally attest to the effectiveness of our internal control over financial reporting until after we are no longer an “ " emerging growth company ” " as defined in the **Jumpstart Our Business Startups Act of 2012 (the"** JOBS Act **")**. 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 internal control over financial reporting is documented, designed or operating. Any failure to maintain effective disclosure controls and internal control over financial reporting could have an adverse effect on our business and results of operations and could cause a decline in the price of our common stock. **If we fail to establish and maintain effective internal control over financial reporting, we may not be able to accurately report our financial results, which may cause investors to lose confidence in our reported financial information and may lead to a decline in the market price of our stock.** Pursuant to Section 404 of the Sarbanes- Oxley Act **("** of 2002, or Section 404 **")** , we are required to furnish a report by our management on our internal control over financial reporting. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we are engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. We identified a material weakness our internal control over financial reporting related to the inaccurate accounting for the value of shares to be issued to the underwriter at the closing of our IPO as well as inaccurate accounting for certain accrued expenses and prepaid expenses and the Company’ s restatement of its **our** financial statements to reclassify all redeemable equity instruments to temporary equity from permanent equity. Up to and including the third fiscal quarter of 2021, our disclosure controls and procedures were not effective. We have implemented a remediation plan , described under Part I, Item 4, Evaluation of Disclosure Controls and Procedures of our Form 10- Q for the third quarter of 2021, to remediate the material weakness but can give no assurance that the measures we have taken will prevent any future material weaknesses or deficiencies in internal control over financial reporting. Even though we believe we have strengthened our controls and procedures, in the future those controls and procedures may not be adequate to prevent or identify irregularities or errors or to facilitate the fair presentation of our financial statements. Risks Related to Our Organizational Structure **Our executive chairman of the board of directors, David Perry has significant influence over the Company.** As of December 31, 2021 **2022** , Mr. Perry and Mr. Appelbaum own **owns** , collectively, approximately **46** 56. 4 % of the outstanding shares of our common stock. As long as such persons each **Mr. Perry either** own **owns** or control **controls** a significant percentage of outstanding voting power, they have **he has** the ability to strongly influence all corporate actions requiring stockholder approval, including the election and removal of directors and the size of our board of directors, any amendment of our certificate of incorporation or bylaws, or the approval of any merger or other significant corporate transaction, including a sale of substantially all of our assets **and** . Some of these persons or entities may have interests different than yours. Delaware law and our governing documents contain certain provisions, including anti- takeover provisions, that limit the ability of stockholders to take certain actions and could delay or discourage takeover attempts that stockholders may consider favorable. Our governing documents and the Delaware General Corporation Law (“ DGCL ”), contain provisions that could have the effect of rendering more difficult, delaying, or preventing an acquisition deemed undesirable by the **our** Board **board of directors** and therefore depress the trading price of our common stock. These provisions could also make it difficult for stockholders to take certain actions, including electing directors who are not nominated by the current members of the **our** Board **board of directors** or taking other corporate actions, including effecting changes in our management. Among other things, our governing documents include provisions regarding: • the ability of the **our** Board **board of directors** to issue shares of preferred stock, including “ " blank check ” " preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer; -• the limitation of the liability, and indemnification of our directors and officers; • a prohibition on

stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of stockholders after such date and could delay the ability of stockholders to force consideration of a stockholder proposal or to take action, including the removal of directors; • the requirement that a special meeting of stockholders may be called only by a majority of our entire ~~Board~~ **board of directors** , which could delay the ability of stockholders to force consideration of a proposal or to take action, including the removal of directors; • controlling the procedures for the conduct and scheduling of board of directors and stockholder meetings; • the ability of ~~the~~ **our** ~~Board~~ **board of directors** to amend the bylaws, which may allow ~~the~~ **our** ~~Board~~ **board of directors** to take additional actions to prevent an unsolicited takeover and inhibit the ability of an acquirer to amend the bylaws to facilitate an unsolicited takeover attempt; and • advance notice procedures with which stockholders must comply to nominate candidates to ~~the~~ **our** ~~Board~~ **board of directors** or to propose matters to be acted upon at a stockholders' meeting, which could preclude stockholders from bringing matters before annual or special meetings of stockholders and delay changes in ~~the~~ **our** ~~Board~~ **board of directors** , and also may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer' s own slate of directors or otherwise attempting to obtain control of us. These provisions, alone or together, could delay or prevent hostile takeovers and changes in control or changes in ~~the~~ **our** ~~Board~~ **board of directors** or management. Our amended and restated bylaws designate specific courts as the exclusive forum for certain litigation that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us. Pursuant to our amended and restated bylaws, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the sole and exclusive forum for state law claims for (1) any derivative action or proceeding brought on our behalf; (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, or other employees to us or our stockholders; (3) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law or our certificate of incorporation or bylaws (including the interpretation, validity or enforceability thereof); or (4) any action asserting a claim governed by the internal affairs doctrine. We refer to this provision in our bylaws as the Delaware Forum Provision. The Delaware Forum Provision will not apply to any causes of action arising under the Securities Act or the Exchange Act. Our amended and restated bylaws further provide that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States shall be the sole and exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. We refer to this provision in our bylaws as the Federal Forum Provision. In addition, our amended and restated bylaws provide that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock is deemed to have notice of and consented to the Delaware Forum Provision and the Federal Forum Provision; provided, however, that stockholders cannot and will not be deemed to have waived our compliance with the U. S. federal securities laws and the rules and regulations thereunder. The Delaware Forum Provision and the Federal Forum Provision in our bylaws may impose additional litigation costs on stockholders in pursuing any such claims. Additionally, these forum selection clauses may limit our stockholders' ability to bring a claim in a judicial forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage the filing of lawsuits against us and our directors, officers and employees, even though an action, if successful, might benefit our stockholders. In addition, while the Delaware Supreme Court ruled in March 2020 that federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court are " **"** facially valid " **"** under Delaware law, there is uncertainty as to whether other courts will enforce our Federal Forum Provision. If the Federal Forum Provision is found to be unenforceable, we may incur additional costs associated with resolving such matters. The Federal Forum Provision may also impose additional litigation costs on stockholders who assert that the provision is not enforceable or invalid. The Court of Chancery of the State of Delaware and the federal district courts of the United States may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders. ~~Risks Related to Our~~ **The price of our** ~~Common~~ **common** ~~Stock~~ **stock** ~~Unstable~~ **may fluctuate due to a variety of factors, including: • changes in the industries in which we and our customers operate; • variations in our operating performance and the performance of our competitors in general; • material and adverse impact of the ongoing COVID-19 pandemic and economic and political developments, including the war in Ukraine, rising interest rates and high inflation, on the markets and the broader global economy; • actual or anticipated fluctuations in our quarterly or annual operating results; • publication of research reports by securities analysts about us or our competitors or our industry; • the public' s reaction to our press releases, our other public announcements and our filings with the SEC; • our failure or the failure of our competitors to meet analysts' projections or guidance that we or our competitors may give to the** market **; • additions** and **departures of key personnel; • changes in laws and regulations affecting our business; • commencement of, or involvement in, litigation involving us; • changes in our capital structure, such as future issuances of securities or the incurrence of additional debt; • the volume of shares of our common stock available for public sale; and • general** economic **and political** conditions ~~may have series adverse consequences on~~ **such as recessions, interest rates, fuel prices, foreign currency fluctuations, international tariffs, social, political and economic risks and acts of war** ~~our~~ **or** ~~business, financial condition~~ **terrorism. These market** and **industry factors may materially reduce the market price of our common** stock ~~price~~ **regardless of our operating performance** . As widely reported, global credit and financial markets have experienced extreme volatility and disruptions in the past several years, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in the rate of inflation, increases in unemployment rates and uncertainty about economic stability, including most recently in connection with the ongoing and evolving COVID- 19 pandemic **and economic and political developments, including the conflict in Ukraine, rising interest rates and high inflation** . There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. Our business could ~~be~~ also be

impacted by volatility caused by geopolitical events, such as the conflict in Ukraine. If the current equity and credit markets deteriorate, or do not improve, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive. Furthermore, our stock price may decline due in part to the volatility of the stock market and the general economic downturn. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay, scale back or discontinue the development and commercialization of one or more of our product candidates **or delay our pursuit of potential in- licenses or acquisitions** . **In addition,** ~~There~~ **there is a risk** ~~can be no assurance~~ that **one** ~~we will be able to comply with the continued listing standards of Nasdaq. If Nasdaq delists our~~ **or more of our current service providers or other partners may not survive these difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget. Recent volatility in capital markets and lower market prices for our securities may affect our ability to access new capital through sales of** shares of **our** common stock **or issuance of indebtedness, which may harm our liquidity, limit our ability to grow our business, pursue acquisitions or improve our operating infrastructure and restrict our ability to compete in our markets. Our operations consume substantial amounts of cash, and we intend to continue to make significant investments to develop and, if approved, commercialize our product candidates, support our business growth, retain or expand our current levels of personnel, enhance our operating infrastructure, and potentially acquire complementary businesses and technologies. Our future capital requirements may be significantly different** from ~~trading~~ **our current estimates and will depend** on **many factors, including the need to: • finance unanticipated working capital requirements; • develop and, if approved, commercialize our product candidates and develop and maintain platform; • pursue acquisitions or other strategic relationships; and • respond to competitive pressures. Accordingly, we may need to pursue equity or debt financings to meet our capital needs. With uncertainty in the capital markets and other factors, such financing may not be available on terms favorable to us or at all. If we raise additional funds through further issuances of equity or convertible debt securities, our existing stockholders could suffer significant dilution, and any new equity securities we issue could have rights, preferences, and privileges superior to those of holders of our common stock. Any debt financing secured by us in the future could involve restrictive covenants relating to our capital- raising activities and other financial and operational matters, which may make** ~~its~~ **it** ~~exchange~~ **more difficult** for ~~failure~~ **us** to **obtain additional capital** ~~meet Nasdaq' s listing standards, we~~ and **to pursue business opportunities, including potential acquisitions. If we are unable to obtain adequate financing** ~~our~~ **or** ~~stockholders~~ **financing on terms satisfactory to us, we** could face significant **limitations on** ~~material adverse consequences including: • a limited availability of market quotations for~~ our ~~securities; • reduced liquidity for our securities; • a determination that our common stock is a " penny stock " which will require brokers trading in our common stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our securities; • a limited amount of news and analyst coverage; and • a decreased~~ ability to **invest in** ~~issue additional securities or~~ **our** ~~obtain additional financing in the future. The price of our common stock may fluctuate due to a variety of factors, including: • changes in the industries in which we and our customers operate; • variations in its operating~~ **operations** ~~performance~~ and **otherwise suffer harm** ~~the performance of our competitors in general; • material and adverse impact of the ongoing COVID- 19 pandemic on the markets and the broader global economy; • actual or anticipated fluctuations in our quarterly or annual operating results; • publication of research reports by securities analysts about us or our competitors or its industry; • the public' s reaction~~ to ~~our press releases, our other public announcements and our filings with the SEC; • our failure or the failure of our competitors to meet analysts' projections or guidance that we or our competitors may give to the market; • additions and departures of key personnel; • changes in laws and regulations affecting~~ our business ~~; • commencement of, or involvement in, litigation involving us; • changes in our capital structure, such as future issuances of securities or the incurrence of additional debt; • the volume of shares of our common stock available for public sale; and • general economic and political conditions such as recessions, interest rates, fuel prices, foreign currency fluctuations, international tariffs, social, political and economic risks and acts of war or terrorism. These market and industry factors may materially reduce the market price of our common stock regardless of our operating performance. Reports published by analysts, including projections in those reports that differ from our actual results, could adversely affect the price and trading volume of our common shares. Securities research analysts may establish and publish their own periodic projections for us. These projections may vary widely and may not accurately predict the results we actually achieve. Our share price may decline if our actual results do not match the projections of these securities research analysts. Similarly, if one or more of the analysts who write reports on us downgrades our stock or publishes inaccurate or unfavorable research about our business, our share price could decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, our share price or trading volume could decline~~ . A significant portion of our total outstanding shares ~~are restricted from immediate resale but~~ may be sold into the market **, which** ~~in the near future. This~~ could cause the market price of our common stock to ~~drop~~ **decline** significantly, even if our business is doing well. Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. **As** ~~Although certain stockholders will be subject to certain restrictions regarding the transfer~~ of ~~our~~ **December 31, 2022, we had outstanding 23, 851, 022 shares of** common stock, **which may be resold in** ~~these~~ **the public market immediately without restriction, subject only to the restrictions of Rule 144 under the Securities Act. If our stockholders sell, or the market perceives that our stockholders intend to sell, substantial amounts of our** shares ~~may be sold after the expiration~~ of **common stock in** the **public market** ~~lock- up. As restrictions on resale end and the registration statements are available for use~~ , the market price of our common stock could decline **significantly** ~~if the holders of currently restricted shares sell them or are perceived by the market as intending to sell them~~ . Our issuance of additional capital stock in connection with financings, acquisitions, investments, our stock incentive plans or otherwise will dilute all other stockholders. We expect to issue additional capital stock in the future that will result in

dilution to all other stockholders. We expect to grant equity awards to employees, directors, and consultants under our stock incentive plans. We may also raise capital through equity financings in the future. As part of our business strategy, we may acquire or make investments in complementary companies, products, or technologies and issue equity securities to pay for any such acquisition or investment. Any such issuances of additional capital stock may cause stockholders to experience significant dilution of their ownership interests and the per share value of our common stock to decline. Because we have no current plans to pay cash dividends on our common stock, you may not receive any return on investment unless you sell your common stock for a price greater than that which you paid for it. We have no current plans to pay cash dividends on our common stock. The declaration, amount and payment of any future dividends will be at the sole discretion of our board of directors. Our board of directors may take into account general and economic conditions, our financial condition and operating results, our available cash, current and anticipated cash needs, capital requirements, contractual, legal, tax and regulatory restrictions, implications on the payment of dividends by us to our stockholders or by our subsidiary to us and such other factors as our board of directors may deem relevant. In addition, the terms of our loan agreement with Hercules Capital restrict our ability to pay cash dividends. Accordingly, we may not pay any dividends on our common stock in the foreseeable future. Future offerings of debt or equity securities by us may adversely affect the market price of our common stock. In the future, we may attempt to obtain financing or to further increase our capital resources by issuing additional shares of our common stock or offering debt or other equity securities, including commercial paper, medium- term notes, senior or subordinated notes, debt securities convertible into equity or shares of preferred stock. Future acquisitions could require substantial additional capital in excess of cash from operations. We would expect to obtain the capital required for acquisitions through a combination of additional issuances of equity, corporate indebtedness and / or cash from operations. Issuing additional shares of our common stock or other equity securities or securities convertible into equity may dilute the economic and voting rights of our existing stockholders or reduce the market price of our common stock or both. Upon liquidation, holders of such debt securities and preferred shares, if issued, and lenders with respect to other borrowings would receive a distribution of our available assets prior to the holders of our common stock. Debt securities convertible into equity could be subject to adjustments in the conversion ratio pursuant to which certain events may increase the number of equity securities issuable upon conversion. Preferred shares, if issued, could have a preference with respect to liquidating distributions or a preference with respect to dividend payments that could limit our ability to pay dividends to the holders of our common stock. Our decision to issue securities in any future offering will depend on market conditions and other factors beyond our control, which may adversely affect the amount, timing and nature of our future offerings. **General Risk Factors Our success depends largely upon the continued services of our key executive officers. These executive officers are at- will employees and therefore they may terminate employment with us at any time with no advance notice. We rely on our leadership team in the areas of operations, clinical and software development, information security, marketing, compliance and general and administrative functions. From time to time, there may be changes in our executive management team resulting from the hiring or departure of executives, which could disrupt our business. The loss of one or more of the members of our senior management team, or other key employees, could harm our business. The replacement of one or more of our executive officers or other key employees would likely involve significant time and costs and may significantly delay or prevent the achievement of our business objectives. To continue to execute our growth strategy, we also must attract and retain highly skilled personnel. Competition is intense for qualified professionals. We may not be successful in continuing to attract and retain qualified personnel. We have from time to time in the past experienced, and we expect to continue to experience in the future, difficulty in hiring and retaining highly skilled personnel with appropriate qualifications. The pool of qualified personnel with experience working in the healthcare market is limited overall. In addition, many of the companies with which we compete for experienced personnel have greater resources than we have. Additionally, our success is dependent on our ability to evolve our culture, align our talent with our business needs, engage our employees and inspire our employees to be open to change and innovation. Our business would be adversely affected if we fail to adequately plan for succession of our executives and senior management, or if we fail to effectively recruit, integrate, retain and develop key talent and / or align our talent with our business needs, in light of the current rapidly changing environment. We qualify as an" emerging growth company" and as a" smaller reporting company", and if we take advantage of certain exemptions from disclosure requirements available to emerging growth companies or smaller reporting companies, which could make our securities less attractive to investors and may make it more difficult to compare our performance to the performance of other public companies. We qualify as an" emerging growth company" as defined in Section 2 (a) (19) of the Securities Act, as modified by the JOBS Act. As such, we are eligible for and intend to take advantage of certain exemptions from various reporting requirements applicable to other public companies that are not emerging growth companies for as long as we continue to be an emerging growth company, including (i) the exemption from the auditor attestation requirements with respect to internal control over financial reporting under Section 404 (b) of the Sarbanes- Oxley Act, (ii) the exemptions from say- on- pay, say- on- frequency and say- on- golden parachute voting requirements and (iii) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We will remain an emerging growth company until the earliest of (i) the last day of the fiscal year in which the market value of the shares of our common stock that are held by non- affiliates exceeds $ 700 million as of June 30 of that fiscal year, (ii) the last day of the fiscal year in which we have total annual gross revenue of $ 1. 235 billion or more during such fiscal year, (iii) the date on which we have issued more than $ 1 billion in non- convertible debt in the prior three- year period or (iv) the last day of the fiscal year following the fifth anniversary of the date of the first sale of our common stocks in our IPO. In addition, Section 107 of the JOBS Act also provides that an emerging growth company can take advantage of the exemption from complying with new or revised accounting standards provided in Section 7 (a) (2) (B) of the Securities Act as long as we are an emerging growth company. An emerging growth company can therefore delay the adoption of certain accounting**

standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption from new or revised accounting standards and, therefore, we may not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. Investors may find our common stock less attractive because we will rely on these exemptions, which may result in a less active trading market for our common stock and our stock price may be more volatile. We are also a" smaller reporting company," meaning that the market value of our stock held by non- affiliates is less than $ 700 million as of the prior June 30 and our annual revenue is less than $ 100 million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market value of our stock held by non- affiliates is less than $ 250 million as of the prior June 30 or (ii) our annual revenue is less than $ 100 million during the most recently completed fiscal year and the market value of our stock held by non- affiliates is less than $ 700 million as of the prior June 30. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10- K and take advantage of reduced disclosure obligations regarding executive compensation. We will continue to incur significant increased expenses and administrative burdens as a public company, which could have an adverse effect on our business, financial condition and results of operations. As a public company, we will continue to face increased legal, accounting, administrative and other costs and expenses as a public company that we did not incur as a private company. The Sarbanes- Oxley Act, including the requirements of Section 404, as well as rules and regulations subsequently implemented by the SEC, the Dodd- Frank Wall Street Reform and Consumer Protection Act of 2010 and the rules and regulations promulgated and to be promulgated thereunder (the" PCAOB") and the securities exchanges, impose additional reporting and other obligations on public companies. Compliance with public company requirements will increase costs and make certain activities more time- consuming. A number of those requirements will require us to carry out activities we have not done previously. In addition, additional expenses associated with SEC reporting requirements will be incurred. Furthermore, if any issues in complying with those requirements are identified (for example, if the auditors identify a material weakness or significant deficiency in the internal control over financial reporting), we could incur additional costs rectifying those issues, and the existence of those issues could adversely affect our reputation or investor perceptions of it. It may also be more expensive to obtain director and officer liability insurance. Risks associated with our status as a public company may make it more difficult to attract and retain qualified persons to serve on our board of directors or as executive officers. The additional reporting and other obligations imposed by these rules and regulations will increase legal and financial compliance costs and the costs of related legal, accounting and administrative activities. These increased costs will require us to divert a significant amount of money that could otherwise be used to expand the business and achieve strategic objectives. Advocacy efforts by stockholders and third parties may also prompt additional changes in governance and reporting requirements, which could further increase costs. There can be no assurance that we will be able to comply with the continued listing standards of Nasdaq. If Nasdaq delists our shares of common stock from trading on its exchange for failure to meet Nasdaq' s listing standards, we and our stockholders could face significant material adverse consequences including: • a limited availability of market quotations for our securities; • reduced liquidity for our securities; • a determination that our common stock is a" penny stock" which will require brokers trading in our common stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our securities; • a limited amount of news and analyst coverage; and • a decreased ability to issue additional securities or obtain additional financing in the future. Reports published by analysts, including projections in those reports that differ from our actual results, could adversely affect the price and trading volume of our common shares. Securities research analysts may establish and publish their own periodic projections for us. These projections may vary widely and may not accurately predict the results we actually achieve. Our share price may decline if our actual results do not match the projections of these securities research analysts. Similarly, if one or more of the analysts who write reports on us downgrades our stock or publishes inaccurate or unfavorable research about our business, our share price could decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, our share price or trading volume could decline.