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

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

We anticipate, however, that federal and state governments will continue to review and assess alternative healthcare delivery systems and payment methodologies, and that public debate regarding these issues will continue in the future. Changes in the law or new interpretations of existing laws can have a substantial effect on permissible activities, the relative costs associated with doing business in the healthcare industry, and the amount of reimbursement available from government and other payors. Any repeal or modification of the Health Reform Laws may materially adversely impact our business, financial condition, results of operations, cash flow, capital resources and liquidity. In addition, the potential proposals for alternative legislation to replace the Health Reform Laws may have an adverse impact on our business. Anti- Bribery and Corruption Laws We are subject to the Foreign Corrupt Practices Act (" FCPA "). We are required to comply with the FCPA, which generally prohibits covered entities and their intermediaries from engaging in bribery or making other prohibited payments to foreign officials for the purpose of obtaining or retaining business or other benefits. In addition, the FCPA imposes accounting standards and requirements on publicly traded U. S. corporations and their foreign affiliates, which are intended to prevent the diversion of corporate funds to the payment of bribes and other improper payments, and to prevent the establishment of " off books " slush funds from which such improper payments can be made. We also are subject to similar anticorruption legislation implemented in Europe under the Organization for Economic Co- operation and Development' s Convention on Combating Bribery of Foreign Public Officials in International Business Transactions. **- 22-** Human Capital Resources As of December 31, ~~2022~~ **2023** , we had ~~154~~ **114** full ~~- time employees and 9 part -~~ time employees. None of our employees are represented by a union. We consider our relations with our employees to be good but we do have a Whistleblower Hotline setup for employees to confidentially report concerns. Of our current employees, approximately **three** ~~, seven~~ are part of finance and accounting, ~~seven~~ **nine** are involved in senior management, ~~20~~ **10** in sales and marketing, one in research, development and regulatory and ~~128~~ **91** in **operations. Our headcount has been significantly reduced in the past year as part of our cost cutting initiatives, and restructuring of our** operations. We value the importance of retention, growth and development of our employees and we believe we offer competitive compensation (including salary, incentive bonus, and equity) and benefits packages. We traditionally will benchmark compensation with external sources to verify **that** positions are paid in- line with the market. Our corporate culture is built on passion ~~-~~ – we believe in the company' s vision of ridding the world of sleep apnea and hire employees who want to share that same passion. We hold annual company- wide ~~trainings~~ - **training courses** and host regularly scheduled management meetings where management communicates notable corporate developments to be disseminated to employees, as well as ~~a~~ periodic corporate all hands meetings. We **are always looking** ~~hire new employees based on merit and qualifications~~ for **additional ways to diversify** ~~the job, regardless of ethnicity, race, gender, religion, sexual preference, or~~ **our** ~~any other non- job related criteria. We thus have created both a diverse and highly skilled~~ workforce. We will continue to promote a work environment that is based on the fundamental principles of human dignity, equality and mutual respect. In addition, we are committed to providing a safe and healthy work environment for all of our employees. In response to the COVID- 19 pandemic, we ~~encouraged employees to work closely with their personal physicians to determine whether or not to receive the vaccine, and we~~ have **required** ~~followed the most current science with respect to the use of~~ personal protective equipment ~~such as masks, social distancing, etc~~ **for patient- facing employees in addition to requiring daily health questionnaires and temperature checks** . Many employees work remotely ~~and when appropriate~~ , **and** we have limited travel as a result of the pandemic. We will continue to support our workforce during these unprecedented circumstances to ensure their safety and well- being. Corporate History Formation We were originally organized on July 7, 2016 in Wyoming as Corrective BioTechnologies, Inc. On September 6, 2016, we changed our name from Corrective BioTechnologies, Inc. to Vivos BioTechnologies, Inc. On March 2, 2018, we changed our name from Vivos BioTechnologies, Inc. to Vivos Therapeutics, Inc. During our formation in 2016, we issued an aggregate of ~~933~~ **37** , 334 shares of common stock to a group of our founders, including Summit Capital USA (now Upeva, Inc., ~~666~~ **26** , 667 shares), Regal Capital Venture Partners LLC (~~166~~ **6** , 667 shares) and Thomas P. Madden (~~100~~ **4** , 000 shares) at a purchase price of $ 0. ~~0003~~ **01** per share (for an aggregate of $ 280 of proceeds). ~~- 24 -~~ Acquisition of BioModeling Solutions, Inc. and First Vivos, Inc. In August and September 2016, we completed, by way of a share exchange, an agreement to acquire the business and operations of (1) BMS (now a wholly- owned subsidiary), which was engaged in the manufacture and sale of our patented DNA appliance ® and FDA cleared mRNA appliance ® (collectively with special proprietary treatment modalities that comprises The Vivos Method), and (2) First Vivos, Inc., a Texas corporation (" First Vivos "), which proposed to develop and operate a retail chain of Vivos Centers with specially trained dentists that offer The Vivos Method and corroborating physicians. In connection with the share exchange with BMS, we issued 3, 333, 334 shares of common stock to the shareholders of BMS (including, but not limited to, Dr. G. Dave Singh, our founder and former Chief Medical Officer and director, who received 3, 219, 705 shares) in exchange for 12, 423, 500 shares of BMS, which constitutes 100 % ownership interest in BMS. In connection with the share exchange with First Vivos, we issued 3, 333, 334 shares of common stock to the shareholders of First Vivos (including, but not limited to, R. Kirk Huntsman, our co- founder, Chairman of the Board and Chief Executive Officer, who received 1, 833, 334 shares) in exchange for 5, 000 shares of First Vivos, which constitutes 100 % ownership interest in First Vivos. The transaction was accounted for as a reverse acquisition and recapitalization, with BMS as the acquirer for financial reporting and accounting purposes. Upon the consummation of the acquisition, the historical financial statements of BMS became our historical financial statements and continued to be recorded at their historical carrying amounts. **- 23-** Adoption of Stock and Option Award Plan On April 18, 2019, our stockholders approved

the adoption of a stock and option award plan (the " 2019 Plan "), under which ~~333~~ **13** , 334 shares were reserved for future issuance for options, restricted stock awards and other equity awards. On June 18, 2020, our stockholders approved an amendment and restatement of the 2019 Plan to increase the number shares or our common stock available for issuance thereunder by ~~833~~ **33** , ~~333~~ **334** share of common stock such that, after amendment and restatement of the 2019 Plan, ~~1, 166~~ **for a total of 46** , 667 shares of common stock ~~will be~~ available for issuance under the 2019 Plan. ~~The~~ **On September 22, 2023, our stockholders approved an amendment and restatement of the** 2019 Plan ~~permits grants~~ **to increase the number shares or our common stock available for issuance thereunder by 80, 000 shares** of ~~equity~~ **common stock such that, after amendment and restatement of the 2019 Plan, 126, 667 shares of common stock are available for issuance under the 2019 Plan. As of December 31, 2023,** awards ~~to employees, directors, consultants~~ **(in the form of options) for** ~~and~~ **an** ~~other independent contractors~~ **aggregate of 73, 917 shares of common stock have been issued under our 2019 Plan** . Approval of Transfer of Corporate Domicile and Reverse Stock Split On April 18, 2019, our stockholders voted to authorize our ~~Board~~ **board** of ~~Directors~~ **directors** to recapitalize our common stock by way of reverse stock split at a ratio of up to one for three. In addition, on such date, our shareholders also authorized our ~~Board~~ **board** of ~~Directors~~ **directors** to transfer our corporate domicile from Wyoming to another U. S. state. Our ~~Board~~ **board** of ~~Directors~~ **directors** elected not to implement the reverse stock split transfer of corporate domicile at that time. Effective August 12, 2020, we transferred our corporate domicile and became a Delaware corporation pursuant to Section 17- 16- 1720 of the Wyoming Business Corporation Act and Section 265 of the Delaware General Corporation Law. As a result of the transfer of corporate domicile, each share of capital stock of Vivos Wyoming became a share of capital stock of Vivos Delaware on a one- to- one basis, and such shares shall carry the same terms in all material respects as the shares of Vivos Wyoming. The transfer of corporate domicile has heretofore been approved by the ~~Board~~ **board** of ~~Directors~~ **directors** and majority shareholders of Vivos Wyoming. On July 30, 2020, prior to the transfer of our corporate domicile from Wyoming to Delaware, ~~Vivos Wyoming~~ we implemented a one- for- three reverse stock split of our outstanding common stock pursuant to which holders of Vivos Wyoming' s outstanding common stock received one share of common stock for every three shares of common stock held. Unless the context expressly dictates otherwise, all references to share and per share amounts referred to in ~~this~~ **the Annual Report reflect the reverse stock split. On October 25, 2023, we effected a reverse stock split of outstanding shares of common stock at a ratio of 1- for- 25. The reverse stock split, which was approved by the Company' s Board of Directors under authority granted by the Company' s stockholders at the Company' s 2023 Annual Meeting of Stockholders held on September 22, 2023, was consummated pursuant to a Certificate of Amendment filed with the Secretary of State of Delaware on October 25, 2023. Unless the context expressly dictates otherwise, all references to share and per share amounts referred to in the** Annual Report reflect the reverse stock split. Segment Information We manage our business within one reportable segment. Segment information is consistent with how management reviews our business, makes investing and resource allocation decisions, and assesses our operating performance. ~~- 25 -~~ Corporate Information Our principal offices are located at 7921 Southpark Plaza, Suite 210, Littleton, Colorado 80120, and our telephone number is (~~866~~ **844**) ~~908~~ **672** - ~~4867~~ **4357** . Our website is www. vivos. com. Our website and the information on or that can be accessed through such website are not part of this Annual Report on Form 10- K. **- 24-** Available Information We maintain a website at www. vivos. com. You may access our annual reports on Form 10- K, quarterly reports on Form 10- Q, current reports on Form 8- K, and amendments to those reports filed or furnished pursuant to Section 13 (a) or 15 (d) of the Exchange Act with the SEC free of charge at our website as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. The reference to our website address does not constitute incorporation by reference of the information contained on our website, and you should not consider the contents of our website in making an investment decision with respect to our common stock. Item 1A. Risk Factors. Investing in our common stock is highly speculative and involves a significant degree of risk. Before you invest in our securities, you should give careful consideration to the following risk factors, in addition to the other information included in this Annual Report on Form 10- K, including our financial statements and related notes, before deciding whether to invest in our securities. The occurrence of any of the adverse developments described in the following risk factors could materially and adversely harm our business, financial condition, results of operations or prospects. In that case, the trading price of our common stock could decline, and you may lose all or part of your investment. Risks Related to Our Business and Industry Our business has a limited operating history, and we continue to refine our business model, which makes it difficult to evaluate our past performance and future prospects. Moreover, we have recently made significant strategic, operational and staffing changes to our business, and it is impossible to know how or if such changes will affect future revenue and earnings. Our business was formed only in 2016, and therefore there is limited historical data on which to evaluate our company. This is particularly true because our current VIP- focused business model only commenced in mid- 2018. In addition, since the roll out of our VIP- focused business model, we have continued to refine our strategies, for example by experimenting with different VIP enrollment and subscription plans and by adding strategic offerings like OMT. Therefore, there is limited and evolving or differing historical operating data on which to evaluate the results of and prospects for our current business model. We have a history of operating losses and may never achieve cash flow positive or profitable results of operations. Since our inception, we have not been profitable and have incurred significant losses and cash flow deficits. ~~As of~~ **For the fiscal years ended** December 31, **2023 and** 2022, ~~the Company~~ **we reported net losses of $ 13. 6 million and $ 23. 8 million respectively, and negative cash flow from operating activities of $ 11. 9 million and $ 19. 6 million, respectively. As of December 31, 2023, we** had an accumulated deficit of approximately $ ~~79~~ **93** . ~~5~~ **1** million and ended the period with approximately $ ~~3~~ **1** . ~~5~~ **6** million in cash ~~assets~~ **and cash equivalents** . **As of** ~~For the years ended~~ December 31, ~~2022~~ **2023** ~~and 2021, the Company incurred a net loss of approximately $ 23. 8 and $ 20. 3 million, respectively. Net cash used in operating activities amounted to approximately $ 19. 6 million and $ 15. 7 million for the years ended December 31, 2022 and 2021, respectively. As of December 31, 2022~~ , the Company had total liabilities of approximately $ ~~8~~ **10** . ~~9~~ **3** million. We anticipate that we will continue to report losses and negative cash flow until we can substantially increase our revenues, which we may be unable to do. There is

therefore a risk that we will be unable to operate our business in a manner that generate positive cash flow or profit, and our failure to increase our revenues, generate positive cash flow and operate our business profitably would damage our reputation and stock price. ~~- 26-~~ Our VIP program is a relatively new business model for us, and management has limited experience operating this model. Our VIP program is a relatively new business model for us, and members of our management team have only a few years of experience in operating our company through this model. As a result, our historical financial results may not be comparable to future results. Also, we are subject to many risks associated with the VIP business model, some of which we have faced and some which we may be unable to presently identify, such as risks associated pricing, competition, marketing and regulatory matters. Moreover, our ability to onboard new VIPs may be impeded by the investments VIPs must make in adapting their practices to the use of The Vivos Method. We cannot assure you that management will be able to recruit and adopt new VIPs. Any such failure may have an adverse impact on our business, financial condition and results of operations. **- 25-** We will need to raise additional capital **to bolster our stockholders' equity and** to fund and grow our business. Such funding, even if obtained, could result in substantial dilution or significant debt service obligations. We may not be able to obtain additional capital on commercially reasonable terms in a timely manner or at all, which could adversely affect our liquidity, financial position, and ability to continue operations. ~~In order~~ **We have a present need for additional capital** to fund and grow our business, ~~we~~ **as well as to bolster our stockholders' equity for Nasdaq Stock Market purposes. We** will need to obtain additional financing ~~,~~ either through borrowings, private offerings, public offerings, or some type of business combination, such as a merger, or buyout, and there can be no assurance that we will be successful in such pursuits. We may be unable to acquire the additional funding necessary to fund our growth or to continue operating. Accordingly, if we are unable to generate adequate cash from operations, and if we are unable to find sources of funding, it may be necessary for us to sell one or more lines of business or all or a portion of our assets, enter into a business combination, or reduce or eliminate operations. Any of these possibilities, to the extent available, may be on terms that result in significant dilution to our shareholders or that result in our investors losing all of their investment in our company. Even if we are able to raise additional capital, we do not know what the terms of any such capital raising would be. In addition, any future sale of our equity securities would dilute the ownership and control of your shares and could be at prices substantially below prices at which our shares currently trade. Our inability to raise capital, coupled with our inability to generate adequate cash from operations, could require us to significantly curtail or terminate our operations. We may seek to increase our cash reserves through the sale of additional equity or debt securities. The sale of convertible debt securities or additional equity securities could result in additional and potentially substantial dilution to our shareholders. The incurrence of indebtedness would result in increased debt service obligations and could result in operating and financing covenants that would restrict our operations and liquidity and ability to pay dividends. In addition, our ability to obtain additional capital on acceptable terms is subject to a variety of uncertainties. We cannot assure you that financing will be available in amounts or on terms acceptable to us, if at all. Any failure to raise additional funds on favorable terms could have a material adverse effect on our liquidity and financial condition. Additionally, ~~during~~ **starting in** 2022 **and through 2023** , we **have been engaged in an** ~~actively~~ -- **active** ~~began a~~ process of reducing staff, eliminating or renegotiating certain vendor contracts, strategically reorganizing our business and revamping our business model. Further such steps, or even more, may be required before management is satisfied that we are positioned to succeed or even survive, and there is a risk that we will be unable to implement cost cutting programs effectively. We have identified material weaknesses in our internal control over financial reporting. In connection with the audit of our consolidated financial statements for the years ended December 31, **2023,** 2022 and 2021, we and our independent registered public accounting firm identified a material weakness in our internal control over financial reporting. A material weakness is a deficiency, or a combination of deficiencies ~~, within the meaning of PCAOB Auditing Standard AS 2201~~ , in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. **The** ~~For the year ended December 31, 2021, our~~ material weakness **in our case** related to the operating effectiveness of our review controls **in that** ~~. Specifically,~~ we did not put the appropriate resources in place to be able to identify technical accounting issues and perform review functions appropriately. Material errors were also identified in our analysis and review of our VIP contracts for applicable factors to meet the definition of a contract under ASC 606 Contracts with Customers, step 1, and our evaluation of our note receivable with respect to our former Orem dental clinic for impairment in accordance with ASC 310 Receivables. Furthermore, in 2022 we did not put the appropriate resources in place to be able to identify technical accounting issues and perform review functions appropriately related to revenue recognition. Material errors were identified in our ability to determine that its existing revenue recognition policy was consistent with the guidance in ASC 606. After analyzing contracts using the five- step process in ASC 606, we have determined that for both VIP enrollment contracts and Orofacial Myofunctional Therapy (MyoCorrect), modifications to our revenue recognition policies were required in order to identify the performance obligations and recognize the revenue as the performance obligations are satisfied or over the customer life as applicable. ~~- 27-~~ Additionally, we did not put the appropriate resources in place to be able to identify technical accounting issues and perform review functions appropriately. As a consequence, we did not effectively design, implement, and operate process- level control activities related to order- to- cash (including revenue, trade receivables, allowance for doubtful accounts, deferred revenue, and bad debt expense), procure- to- pay (including prepaid expenses), hire- to- pay (including compensation expense), and leases. These control deficiencies resulted in immaterial misstatements, some of which were corrected, in the consolidated financial statements as of and for the year ended December 31, 2022. These control deficiencies, aggregated, create a reasonable possibility that a material misstatement to the consolidated financial statements will not be prevented or detected on a timely basis. **- 26-** In summary, as of December 31, 2022 we identified material weaknesses related to the operating effectiveness of our review controls in that we did not put the appropriate resources in place to be able to identify and account for technical accounting issues and perform review functions appropriately **. For the year ended December 31, 2023, we began to implement a remediation plan to address the material weakness derived from the deficiencies and errors noted above.**

While we believe that at December 31, 2023, we had taken great strides to complete the full remediation of all of our internal control deficiencies and associated material weakness by undertaking the plan described in Item 9A of this Report, we believe that additional review and testing is required in the coming periods during 2024 before we can affirmatively declare that the material weakness has been fully remediated . If we are unable to remedy these or similar material weakness that may arise in the future, or if we generally fail to establish and maintain effective internal controls appropriate for a public company, we may be unable to produce timely and accurate financial statements, and we may continue to conclude that our internal control over financial reporting is not effective, which could adversely impact our investors' confidence and our stock price. Delays in filing our periodic reports have led and could in the future lead to the loss of our ability to use certain " short form " registration statements (including " shelf " registration statements used for more efficient fundraising). We expect to derive a substantial portion of our prospective future revenue from sales of our appliances and treatments, which leaves us reliant on the commercial viability of The Vivos Method. Currently, our primary product is The Vivos Method, inclusive of MyoCorrect ~~,~~ **and** our SleepImage ® HST ~~, and our multidisciplinary protocols for adjunctive therapy~~ . Our secondary source of revenue is our clinical training and practice support programs, including Billing Intelligence Services, Airway Intelligence System and AireO2. We expect that sales of the component aspects of The Vivos Method and our services to our VIPs related to the use of such treatments will account for a significant majority of our prospective revenue for the foreseeable future. We currently market and sell our appliances (which are central to The Vivos Method) primarily in the United States and Canada, with a very limited presence in Australia. The Vivos Method is different from current surgical and non- surgical treatments dentofacial abnormalities and / or mild to ~~moderate~~ **severe** OSA and snoring, therefore we cannot assure you that dentists in corroboration with physicians will use The Vivos Method or become VIPs, and demand for The Vivos Method may decline or may not increase as quickly as we expect. Also, we cannot assure you that The Vivos Method will compete effectively as a treatment alternative to other more well- known and well- established therapies, such as CPAP, mandibular advancement, or palatal surgical procedures. Since The Vivos Method currently represents our primary product, and since our VIP program is our primary means of commercialization, we are significantly reliant on the level of recurring sales of The Vivos Method treatment and decreased or lower than expected sales or recruitment and ~~integration~~ **maintenance** of new VIPs would cause us to lose all or substantially all of our revenue. A material portion of our future revenue is expected to derive from sales and enrollments of new dentists into our Vivos Integrated Practice (VIP) program, including dentists who are part of a ~~Dental Service Organization (~~ DSO ~~)~~ which leaves us reliant on the willingness of dentists and / or DSO groups to continue to enroll. We believe that The Vivos Method is the first commercially available treatment based on our proprietary technology for the treatment of dentofacial abnormalities and / or mild to ~~moderate~~ **severe** OSA. Our success depends both on the sufficient acceptance and adoption by the medical / dental community of The Vivos Method as a non- invasive treatment for the treatment of dentofacial abnormalities and / or mild to ~~moderate~~ **severe** OSA. Currently, a relatively limited number of dentists and other medical clinicians provide treatment with The Vivos Method. We cannot predict how quickly, if at all, the medical / dental community will accept The Vivos Method, or, if accepted, the extent of its use. For us to be successful: ● our dentist customers and referring physicians must believe that The Vivos Method offers meaningful clinical and economic benefits for the treating provider and for the patient as compared to the other surgical and non- surgical procedures or devices currently being used to treat individuals with dentofacial abnormalities and / or mild to ~~moderate~~ **severe** OSA and referring physicians must write a prescription for the use of a Class II Vivos appliance; ~~- 28 -~~ ● our dentist customers must believe patients will pay for The Vivos Method out- of- pocket, and patients must believe that paying out- of- pocket for treatment in The Vivos Method is the best alternative to either doing nothing or entering into another treatment option; and ● Our dentist customers must be willing to pay us for the right to become VIPs and to commit the time and resources required to learn the new clinical and technical skills and invest in the technology required to treat patients with dentofacial abnormalities and / or mild to ~~moderate~~ **severe** OSA using The Vivos Method. Independent dentists as well as dentists affiliated with a DSO may not desire to continue to enroll in our VIP or DSO program. **- 27-** In reference to the treatment of mild to ~~moderate~~ **severe** OSA and snoring, studies have shown that a significant percentage of people who have OSA remain undiagnosed and therefore do not seek treatment. Many of those patients who are diagnosed with OSA may be reluctant to seek treatment because of the significant costs of treatment given the less severe nature of their condition, the potentially negative lifestyle effects of traditional treatments, and the lack of awareness of new treatment options. If we are unable to increase public awareness of the prevalence of OSA or if the medical / dental community is slow to adopt or fails to adopt The Vivos Method as a treatment for their patients, we would suffer a material adverse effect on our business, financial condition and results of operations. The failure of large U. S. customers or ~~Dental Service Organizations (~~ DSO ~~)~~ to pay for their purchases of The Vivos Method products and services on a timely basis could reduce our future sales revenue and negatively impact our liquidity. The timing and extent of our future growth in sales revenue depends, in part, on our ability to continue to increase the number of U. S. dentists using The Vivos Method, as well as expanding the number of The Vivos Method treatments used by these physicians / dentists. To the extent one or more of our large U. S. dentist customers or DSO groups fails to pay us on a timely basis, we may be required to discontinue selling to these organizations and find new customers, which could reduce our future sales revenue and negatively impact our liquidity. We face risks **from negative publicity from unregistered oral appliances which has and may continue to hurt our sales. On or about March 1, 2023, CBS News reported the tragic case of a woman with a malocclusion and breathing problem who had received treatment via a fixed oral appliance known as the AGGA (Anterior Growth Guidance Appliance). According to the televised CBS report, the device created serious issues with her dentition and jaws, resulting in the loss of several anterior teeth. The patient filed a $ 10 million lawsuit against the treating dentist. News of this lawsuit quickly spread throughout the country, and particularly within the dental and orthodontic communities. Within days, rumors and wildly untrue statements were published on social media platforms and elsewhere that began to associate and confuse our appliances with the AGGA. Our company was not named in the lawsuit, nor was our device implicated in**

creating the tooth displacement and other concerns that gave rise to the lawsuit. We have never had any association or affiliation with the AGGA device or its promoters, nor have we ever endorsed these kind of counterfeit fixed oral appliances that make unproven and unsubstantiated claims. The AGGA is a non- FDA cleared oral appliance. We believe that the publicity regarding the AGGA device generated confusion and apprehension amongst both existing VIP dentists and other non- affiliated dentist prospects. We believe that our VIP enrollments and sales of our appliances in the first and second quarter of 2023 decreased as a result of the negative publicity. The persistence of negative publicity regarding the use of oral appliances to treat OSA could continue to have a material adverse effect on our revenue and overall results of operations. The failure to expand our market penetration with DME distribution agreements would adversely affect our revenue and results of operations. During 2023, we entered into distribution collaborations with third parties to expand access of our products to potential patients. We hope that these strategic initiatives will lead to revenue growth opportunities for us in 2024 and beyond, and our ability to capitalize on these initiatives is expected to be a material aspect of our sales and marketing program going forward. These distribution agreements could be subject to the success from a pilot program, and regulatory approvals prior to us being able to fully deploy these arrangements. The failure of any pilot program or to obtain regulatory approval could lead to termination of a DME relationship. Even if our DME distribution arrangements proceed, we may not be able to achieve our planned growth or, even if we are able to expand our market penetration as planned, any new territories may not be profitable or otherwise perform as planned. Failure to successfully implement our growth strategy with DMEs would have an adverse impact on our business, financial condition, and results of operations.- 28- We face risks relating to public health conditions such as the COVID- 19 pandemic, which could adversely affect our dentist customers, our business and our results of operations. Our business and prospects have been and could continue to be materially adversely affected by the COVID- 19 pandemic or recurrences of COVID- 19 (such as has occurred in the fall of 2020 and into 2021 ~~and the first half of 2022~~) or any other similar diseases in the future. Material adverse effects from COVID- 19 and similar diseases could result in numerous known and currently unknown ways including from quarantines and lockdowns which impair our marketing and sales efforts to dentists or other medical professionals. During the COVID- 19 pandemic, dental offices throughout the U. S. and Canada shut down for extended periods of time (and may be shut down again due to ~~government mandates or lockdowns~~ **recurrences of COVID- 19**), thus negatively impacting our product revenues ~~. Such dental practice closures disrupted and dislodged significant portions of the dental workforce, including many hygienists who decided to quit or retire. Such disruptions to dental practices has had a negative and ongoing impact on our VIP offices' ability to educate and inform patients about their OSA and The Vivos Method~~ . The pandemic and reactions to the pandemic or future outbreaks of COVID- 19 and variants of COVID- 19 could also impair the timing of obtaining necessary consents and approvals from the FDA, as its employees could also be under such quarantines and lockdowns and their time could be mandatorily required to be allocated to more immediate global and domestic concerns relating to COVID- 19. In addition, we purchase materials for our products from suppliers located in affected areas, and we may not be able to procure required components or secure manufacturing capability. The effects of the COVID- 19 pandemic have also placed travel restrictions on us and our VIPs, as well as temporary closures of the facilities of our suppliers and our VIPs as non- essential medical and dental procedures have been limited, which could also adversely impact our business. In addition, a significant outbreak of contagious diseases in the human population could result in a widespread health crisis that could adversely affect the economies and financial markets of many countries, resulting in an economic downturn that could reduce the demand for our products and impair our business prospects including as a result of being unable to raise additional capital on acceptable terms to us, if at all. ~~- 29-~~ We may not be able to successfully implement our growth strategy for our VIPs on a timely basis or at all, which could harm our business, financial condition, and results of operations. The growth of our VIP base depends on our ability to execute our plan to recruit and enroll new VIPs. Our ability to recruit and enroll VIPs depends on many factors, including our ability to: ● achieve brand awareness in new and existing markets; ● convince potential VIPs of the value of our products and services and to make the required investments in becoming a VIP and using The Vivos Method; ● manage costs, which could give rise to delays or cost overruns; ● recruit, train, and retain qualified dentists, dental hygienists, physicians, physician assistants, medical technologists and other staff in our local markets; ● obtain favorable reimbursement rates for services rendered at VIP offices; ● outperform competitors; and ● maintain adequate information systems and other operational system capabilities. ~~● demonstrate convincingly that the investment of time, training, and money in becoming a VIP will have a tangible and significant ROI for the provider.~~ Further, applicable laws, rules and regulations (including licensure requirements) could negatively impact our ability to recruit and enroll VIPs. Accordingly, we may not be able to achieve our planned growth or, even if we are able to grow our VIP base as planned, any new VIPs may not be profitable or otherwise perform as planned. Failure to successfully implement our growth strategy would likely have an adverse impact on our business, financial condition, and results of operations. The long- term success of our VIP program is highly dependent on our ability to successfully identify, recruit and enroll target independent dental practices as well as to convince other medical professionals to participate in the treatment of OSA with our products and services. To achieve our growth strategy, we will need to identify, recruit, and enroll new VIPs and have them operate on a profitable and recurring basis. We consider numerous factors in identifying target markets where we can enter or expand. The number and timing of new VIPs enrolled during any given period may be negatively impacted by several factors including, without limitation: ● the identification and availability of attractive practices to be VIPs; **- 29-** ● our ability to successfully identify and address pertinent risks and benefits during the onboarding process, including designing, implementing and as necessary modifying pricing programs for VIP enrollment and subscription fees that are acceptable to dental practices; ● the proximity of VIPs to one of our or our competitors' existing centers; ● our VIP' s ability to obtain required governmental licenses, permits and authorizations on a timely basis; and ● our VIP' s ability to recruit qualified dentists, dental hygienists, physicians, physician assistants, medical technologists and other personnel to staff their practices using The Vivos Method. If we are unable to find and onboard ~~attractive~~ VIPs in existing markets or new

markets, our revenue and profitability may be harmed, we may not be able to implement our growth strategy and our financial results may be negatively affected. Moreover, we have begun to expand marketing and related efforts to medical professional beyond the dentistry community. We may be unable to convince medical sleep specialists, cardiologists, pediatric sleep specialists, chiropractors, nutritionists and other professionals of the benefits of The Vivos Method specifically and a multidisciplinary approach to treating OSA in general. Our inability to ~~implementing~~ --- **implement strategies in increase our VIP enrollments or generate interest from other medical professionals who could refer patients to our VIPs would have a material adverse effect on our revenues and results of operations** . ~~- 30 -~~ Our future operating results are difficult to predict and may vary significantly from quarter to quarter, which may adversely affect the price of our common stock. Our limited history of sales of The Vivos Method and VIP enrollments and subscriptions, together with our history of losses, make prediction of future operating results difficult. You should not rely on our past revenue growth as any indication of future growth rates or operating results. Our valuation and the price of our securities **will** likely ~~will~~ fall in the event our operating results (notably our revenue growth, with the goal of achieving cash flow positive and profitable operations) do not meet the expectations of analysts and investors. Comparisons of our quarterly operating results are an unreliable indication of our future performance because they are likely to vary significantly based on many factors, including: ● our inability to attract demand for and obtain acceptance of The Vivos Method for the treatment of dentofacial abnormalities and / or mild to ~~moderate~~ **severe** OSA and snoring by both medical professionals and their patients; ● the success of alternative therapies and surgical procedures to treat individuals, and the possible future introduction of new products and treatments; ● our ability to design, implement and as necessary modifying pricing programs for VIP enrollment and subscription fees; ● our ability to expand by adding additional VIPs in leading major metro areas; ● the expansion and rate of success of our marketing and advertising efforts to both consumers and dentists as well as other medical professionals, and the rate of success of our direct sales force in the United States and internationally; ● Failure of third- party contract manufacturers to deliver products or provide services in a cost effective and timely manner; ● our failure to develop, find or market new products; ● the successful completion of current and future clinical studies, and the possibility that the results of any future study may be adverse to our product and services, or reveal some heretofore unknown risk to patients from treatment in The Vivos Method; the failure by us to make professional presentation and publication of positive outcomes data from these clinical studies, and the increased adoption of The Vivos Method by dentists as a result of the data from these clinical studies; **- 30-** ● actions relating to ongoing FDA compliance; ● the size and timing of orders from dentists and independent distributors; ● our ability to obtain reimbursement for The Vivos Method (i. e., billable oral appliances and orofacial myofunctional therapy) in the future from third- party healthcare insurers; ● the willingness of patients to pay out- of- pocket for treatment in The Vivos Method in the absence of reimbursement from third- party healthcare insurers, for; decisions by one or more commercial health insurance companies to preclude, deny, limit, reduce, eliminate, or curtain reimbursement for treatment in whole or part by The Vivos Method; ● unanticipated delays in the development and introduction of our current and future products and / or our inability to control costs; ● the effects of global or local pandemics or epidemics and governmental responses, such as COVID- 19; ~~- 31 -~~ ● seasonal fluctuations in revenue due to the elective nature of sleep ~~related~~ **- disordered** breathing ~~disorder~~ treatments for mild to ~~moderate~~ **severe** OSA, as well as seasonal fluctuations resulting from adverse weather conditions, earthquakes, floods or other acts of nature in certain areas or regions that result in power outages, transportation interruptions, damages to one or more of our facilities, food shortages, or other events which may cause a temporary or long- term disruption in patient priorities, finances, or other matters; and ● general economic conditions as well as those specific to our customers and markets. Therefore, you should expect that our results of operations will be difficult to predict, which will make an investment in our company uncertain. Our MID program may not perform as anticipated or may take longer than expected to gain acceptance. Begun only in 2020, our MID is a new business offering for us, and the model is yet unproven. As a result, actual results may be lower than expected due to lower than expected referrals and other factors. Also, we are subject to many risks associated with this new business model that we are unable to presently identify, such as pricing, competition, marketing and regulatory risks. If we fail to adequately identify and respond to such risks in a timely manner, our financial condition and results of operations could be adversely affected. The SleepImage ® home sleep test used in our VivoScore Program is a relatively new technology which may not be utilized by VIPs to the degree anticipated. The SleepImage ~~®~~ HST used in our VivoScore Program is a relatively new technology which could take longer to gain acceptance within the medical and dental communities. If medical and dental care providers do not utilize this new technology, or if the test is not as effective as anticipated, the financial results from the program may be lower than currently expected. Also, we are subject to many risks associated with this new technology that we are unable to presently identify, such as pricing, competition, marketing and regulatory risks. If we fail to adequately identify and respond to such risks in a timely manner ~~,~~ on our business, financial condition and results of operations could be adversely affected. Moreover, the design and implementation of our VivoScore Program is new, as the current program arose following our renegotiated agreement with MyCardio LLC in early 2022. Therefore, we face the risks associated with establishing a new revenue center as the VivoScore Program itself (under which we lease the SleepImage ~~®~~ ring recorder to dentists) may not attract a following sufficient **enough** to make the program a successful revenue generator for us. **- 31-** We may not be able to respond in a timely and cost- effective manner to changes in consumer preferences. The Vivos Method is subject to changing consumer preferences. A shift in consumer preferences away from the protocol and products we offer would result in significantly reduced revenue. Our future success depends in part on our ability to anticipate and respond to changes in consumer preferences. Failure to anticipate and respond to changing consumer preferences in the products we market could lead to, among other things, lower sales of products, significant markdowns or write- offs of inventory, increased product returns and lower margins. If we are not successful in anticipating and responding to changes in consumer preferences, our results of operations in future periods will be materially adversely impacted. Further clinical studies of our products comprising The Vivos Method may adversely impact our ability to generate revenue if they do not demonstrate that The Vivos Method is clinically effective. We have conducted, and continue to

conduct, a number of clinical studies of the use of The Vivos Method to treat patients with dentofacial abnormalities and / or mild to ~~moderate~~ **severe** OSA in the United States and Canada. We are involved in a number of ongoing clinical studies evaluating clinical outcomes from the use of The Vivos Method including prospective, randomized, placebo- controlled studies, as well as clinical studies that are structured to obtain additional clearances from the FDA for expanded clinical indications for use of The Vivos Method. ~~- 32 -~~ We cannot assure you that these clinical studies will continue to demonstrate that The Vivos Method provides clinical effectiveness for individuals with dentofacial abnormalities and patients diagnosed with mild to ~~moderate~~ **severe** OSA, nor can we assure you that the use of The Vivos Method will prove to be safe and effective in clinical studies under United States or international regulatory guidelines for any expanded indications. Additional clinical studies of The Vivos Method may identify significant clinical, technical or other obstacles that will have to be overcome prior to obtaining clearance from the applicable regulatory bodies to market The Vivos Method for such expanded indications. If further studies of The Vivos Method indicate that it is not a safe and effective, our ability to market The Vivos Method, and generate substantial revenue from additional sales, may be materially limited. Individuals selected to participate in these further clinical studies must meet certain anatomical and other criteria to participate. We cannot assure you that an adequate number of individuals can be enrolled in clinical studies on a timely basis. Further, we cannot assure you that the clinical studies will be completed as planned. A delay in the analysis and publication of the positive outcomes data from these clinical studies, or the presentation or publication of negative outcomes data from these clinical studies, including data related to approval of The Vivos Method for expanded indications, may materially impact our ability to increase revenue through sales and negatively impact our stock price. Our business and results of operations may be impacted by the extent to which patients using The Vivos Method achieve adequate levels of third- party insurance reimbursement. Whenever practical, The Vivos Method is paid for primarily out- of- pocket by patients, with any available health insurance coverage being reimbursed if and as paid at a later date, where the patient is being treated for dentofacial abnormalities and / or mild to ~~moderate~~ **severe** OSA. The cost of treatments for dentofacial abnormalities and / or mild to ~~moderate~~ **severe** OSA, such as CPAP, and most surgical procedures generally are covered and reimbursed in whole or part by third- party healthcare insurers. The Vivos Method is a customized protocol often combined with custom oral appliance therapy, some of which currently qualify for reimbursement. Our ability to generate revenue from additional sales of The Vivos Method for the treatment of dentofacial abnormalities and / or mild to ~~moderate~~ **severe** OSA may be materially limited by the extent to which reimbursement of The Vivos Method is available in the future. In addition, third- party healthcare insurers are increasingly challenging the prices charged for medical products and procedures. If we are successful in our efforts to obtain reimbursement for the billable procedures within The Vivos Method, any changes in this reimbursement system could materially affect our ability to continue to grow our business. **- 32 -** Reimbursement and healthcare payment systems in international markets vary significantly by country and reimbursement for the billable procedures within The Vivos Method may not be available at all under either government or private reimbursement systems. If we are unable to achieve reimbursement approvals in international markets, it could have a negative impact on market acceptance of The Vivos Method and potential revenue growth in the markets in which these approvals are sought. In an effort to help expand in- network insurance coverage for The Vivos Method, in December 2022, we announced a collaboration with Nexus which effectively combines our proprietary out- of- network Billing Intelligence Service with the Nexus' in- network medical billing platform. The goal is to provide both companies' medical professional networks with greater access to both in or out- of- network billing with all major medical insurance companies, facilitating case acceptances, insurance billing procedures and reimbursement. However, our collaboration with Nexus may not achieve the result of expanding insurance coverage for The Vivos Method, which in turn could have an adverse effect on our results of operations (particularly if our outlay of resources in connection with the Nexus collaboration exceed the revenues, if any, generated). Our products and third- party contract manufacturing activities are subject to extensive governmental regulation that could prevent us from selling our appliances or introducing new and / or improved products in the United States or internationally. Our products and third- party contract manufacturing activities are subject to extensive regulation by several governmental agencies, including the FDA and comparable international regulatory bodies. We are required to: ● obtain clearance from the FDA and certain international regulatory bodies before we can market and sell our products; ~~- 33 -~~ ● satisfy all content requirements for the sales and promotional materials associated with The Vivos Method; and ● undergo rigorous inspections of our facilities, manufacturing and quality control processes, records and documentation. Compliance with the rules and regulations of these various regulatory bodies have created regulatory challenges for us in the past and may delay or prevent us from introducing any new models of The Vivos Method or other new products. In addition, government regulations may be adopted that could prevent, delay, modify or rescind regulatory clearance or approval of our products. Our contract manufacturing labs are further required to demonstrate compliance with the FDA' s quality system regulations. The FDA enforce their quality system regulations through pre- approval and periodic post- approval inspections by representatives from the FDA. These regulations relate to product testing, vendor qualification, design control and quality assurance, as well as the maintenance of records and documentation. If we fail to conform to these regulations, the FDA may take actions that could seriously harm our business. These actions include sanctions, including temporary or permanent suspension of our operations, product recalls and marketing restrictions. A recall or other regulatory action could substantially increase our costs, damage our reputation and materially affect our operating results. Our products are currently not recommended by most medical sleep specialists, who are integral to the diagnosis and treatment of sleep breathing disorders. The majority of patients being treated today for OSA, domestically and internationally, are initially referred to pulmonologists or other sleep specialists by their primary care physicians. Pulmonologists or other sleep specialists typically administer a polysomnogram, or overnight sleep study, to diagnose the presence and severity of OSA. If an individual is diagnosed with OSA by a qualified medical doctor, CPAP is typically prescribed as the therapy of choice. Although we offer The Vivos Method through our VIPs, our domestic sales organization does not generally call on sleep specialists or third- party sleep centers to sell The Vivos Method, and we do not believe that most qualified sleep specialists today would recommend The

Vivos Method to their patients with mild to ~~moderate~~ **severe** OSA. We cannot predict the extent to which medical doctors will, in the future, endorse or recommend our protocol to their patients, even for those who are unwilling or unable to comply with other alternative therapies. **- 33-** We face significant competition in the rapidly changing market for treating mild to ~~moderate~~ **severe** OSA and snoring in adults, and we may be unable to manage or respond to competitive pressures. The market for treating mild to ~~moderate~~ **severe** OSA and snoring in adults, is highly competitive and evolving rapidly. According to the American Sleep Apnea Association, over 100 different oral appliances are FDA cleared for the treatment of snoring and mild to ~~moderate~~ **severe** obstructive sleep apnea. The Vivos Method must compete with more established products, treatments and surgical procedures, which may limit our growth and negatively affect our business. Many of our competitors have an established presence in the field and have established relationships with pulmonologists, sleep clinics and ear, nose and throat specialists, which play a significant role in determining which product, treatment or procedure is recommended to the patient. We believe certain of our competitors are attempting to develop innovative approaches and new products for diagnosing and treating OSA and other sleep ~~related~~ **disordered** breathing ~~disorder~~ conditions. We cannot predict the extent to which ENTs, oral maxillofacial surgeons, primary care physicians or pulmonologists would or will recommend The Vivos Method over new or other established devices, treatments or procedures. Moreover, we are in the early stages of implementing our business plan and have limited resources with which to market, develop and sell The Vivos Method. Many of our competitors have substantially greater financial and other resources than we do, including larger research and development staffs who have more experience and capability in conducting research and development activities, testing products in clinical trials, obtaining regulatory approvals and manufacturing, marketing, selling, and distributing products. Some of our competitors may achieve patent protection, regulatory approval, or product commercialization more quickly than we do, which may decrease our ability to compete. If we are unable to be competitive in the market for OSA, our revenue will decline, which would negatively affect our results of operations. ~~- 34-~~ The Vivos Method may become obsolete if we are unable to anticipate and adapt to rapidly changing technology. The medical device industry is subject to rapid technological innovation and, consequently, the life cycle of any particular product can be short. Alternative products, procedures or other discoveries and developments to treat dentofacial abnormalities and / or OSA may render The Vivos Method obsolete. Furthermore, the greater financial and other resources of many of our competitors may permit them to respond more rapidly than we can to technological advances. If we fail to develop new technologies, products, or procedures to upgrade or improve our existing treatments to respond to a changing market before our competitors are able to do so, our ability to market our products and protocol and generate substantial revenue may be limited. Our international sales are subject to a number of risks that could seriously harm our ability to successfully commercialize The Vivos Method in international markets. We do not have significant international sales outside of Canada, although we hope to more broadly introduce The Vivos Method into international markets. Our ability to generate international sales is subject to several risks, including: ● our ability to obtain appropriate regulatory approvals to market The Vivos Method in certain countries; ● our ability to identify new independent third- party distributors in international markets where we do not currently have distributors; ● the impact of recessions in economies outside the United States; ● greater difficulty in negotiating with socialized medical systems, maintaining profit margins comparable to those achieved in the United States, collecting accounts receivable, and longer collection periods; **- 34-** ● unexpected changes in regulatory requirements, tariffs or other trade barriers; ● weaker intellectual property rights protection in some countries; ● potentially adverse tax consequences; and ● political and economic instability. The occurrence of any of these events could seriously harm our future international sales and our ability to successfully commercialize our products in international markets, thereby limiting our growth and revenue. We depend on a few suppliers for key components, making us vulnerable to supply shortages and price fluctuation. We purchase components for The Vivos Method from a variety of vendors on a purchase order basis; we have no long- term supply contracts with any of our vendors. While it is our goal to have multiple sources to procure certain key components, in some cases it is not economically practical or feasible to do so. To mitigate this risk, we maintain an awareness of alternate supply sources that could provide our currently single- sourced components with minimal or no modification to the current version of The Vivos Method, practice supply chain management, maintain safety stocks of critical components and have arrangements with our key vendors to manage the availability of critical components. Despite these efforts, if our vendors are unable to provide us with an adequate supply of components in a timely manner, or if we are unable to locate qualified alternate vendors for components at a reasonable cost, the cost of our products would increase, the availability of our products to our customers would decrease and our ability to generate revenue could be materially limited. ~~- 35-~~ There are risks associated with outsourced production that may hurt our results of operations. We outsource the manufacture of substantially all our products to third- party manufacturers on a case- by- case basis. By law, the selection of the manufacturer is at the sole discretion of the treating dentist. However, we select our approved and certified manufacturers by training and screening them in advance based on their capabilities, supply capacity, reputation, regulatory registration and compliance, and other relevant traits. Most of these manufacturers are located in the U. S., but at least one important manufacturer is located in South Korea, and other smaller manufacturers are located in Canada. In any case, the possibility of delivery delays, product defects, import or customs blockages, and other production- side risks stemming from outsourcers creates the risk that our expenses associated with these issues could unexpectedly increase in any period. In addition, inadequate production capacity among outsourced manufacturers could result in our being unable to supply enough product amid periods of high product demand, the opportunity costs of which could be substantial. All of these risks could have a material adverse effect on our results of operations. We do not have any long- term contracts with manufacturers, suppliers or other service providers for our products. Our business would be harmed if manufacturers and service providers are unable to deliver products or provide services in a timely and cost- effective manner, or if we are unable to timely fulfill orders. We do not have any long- term contracts with contract manufacturers, suppliers or other service providers for our products. We do not anticipate that this will change. As a result, if any manufacturer or supplier is unable, either temporarily or permanently, to manufacture or deliver products or provide services to us in a timely and cost- effective manner, it could have an

adverse effect on our financial condition and results of operations. Our ability to provide effective customer service and efficiently fulfill orders for merchandise depends, to a large degree, on the efficient and uninterrupted operation of the manufacturing and related call centers, distribution centers, and management information systems, some of which are run by third parties. Any material disruption or slowdown in manufacturing, order processing or fulfillment systems resulting from strikes or labor disputes, telephone down times, electrical outages, mechanical problems, human error or accidents, fire, natural disasters, adverse weather conditions or comparable events could cause delays in our ability to receive and fulfill orders and may cause orders to be lost or to be shipped or delivered late. As a result, these disruptions could adversely affect our financial condition or results of operations in future periods. **- 35-** We depend on our patents and proprietary technology, which we may not be able to protect. Our success depends, in part, on our ability to obtain and maintain patent protection for The Vivos Method components and the confidentiality of proprietary clinical treatments. Our success further depends on our ability to obtain and maintain trademark protection for our name and mark; to preserve our trade secrets and know- how; and to operate without infringing the intellectual property rights of others. We cannot assure investors that we will continue to innovate and file new patent applications, or that if filed any future patent applications will result in granted patents We cannot assure you that any of our patents pending will result in issued patents, that any current or future patents will not be challenged, invalidated or circumvented, that the scope of any of our patents will exclude competitors or that the patent rights granted to us will provide us any competitive advantage or protect our products. The patent position of device companies, including ours, is generally uncertain and involves complex legal and factual considerations and, therefore, validity and enforceability cannot be predicted with certainty. Patents may be challenged, deemed unenforceable, invalidated or circumvented. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary technologies, treatments and any future products are covered by valid and enforceable patents or are effectively maintained as trade secrets. ~~- 36-~~ Any patents we have obtained or do obtain may be challenged by re- examination or otherwise invalidated or eventually found unenforceable. Both the patent application process and the process of managing patent disputes can be time consuming and expensive. If we were to initiate legal proceedings against a third party to enforce a patent related to one of our products, the defendant in such litigation could counterclaim that our patent is invalid and / or unenforceable. In patent litigation in the U. S., defendant counterclaims alleging invalidity and / or unenforceability are commonplace, as are validity challenges by the defendant against the subject patent or other patents before the United States Patent and Trademark Office (or USPTO). Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non- enablement, failure to meet the written description requirement, indefiniteness, and / or failure to claim patent eligible subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent intentionally withheld material information from the USPTO, or made a misleading statement, during prosecution. Additional grounds for an unenforceability assertion include an allegation of misuse or anticompetitive use of patent rights, and an allegation of incorrect inventorship with deceptive intent. Third parties may also raise similar claims before the USPTO even outside the context of litigation. The outcome is unpredictable following legal assertions of invalidity and unenforceability. With respect to the validity question, for example, we cannot be certain that no invalidating prior art existed of which we and the patent examiner were unaware during prosecution. These assertions may also be based on information known to us or the USPTO. If a defendant or third party were to prevail on a legal assertion of invalidity and / or unenforceability, we would lose at least part, and perhaps all, of the claims of the challenged patent. Such a loss of patent protection would or could have a material adverse impact on our business. The standards that the USPTO (and foreign equivalents) use to grant patents are not always applied predictably or uniformly and can change. There is also no uniform, worldwide policy regarding the subject matter and scope of claims granted or allowable in device patents. Accordingly, we do not know the degree of future protection for our proprietary rights or the breadth of claims that will be allowed in any patents issued to us or to others. However, there can be no assurance that our technology will not be found in the future to infringe upon the rights of others or be infringed upon by others. Moreover, patent applications are in some cases maintained in secrecy until patents are issued. The publication of discoveries in the scientific or patent literature frequently occurs substantially later than the date on which the underlying discoveries were made and patent applications were filed. Because patents can take many years to issue, there may be currently pending applications of which we are unaware that may later result in issued patents that our products or product candidates infringe. For example, pending applications may exist that provide support or can be amended to provide support for a claim that results in an issued patent that our product infringes. In such a case, others may assert infringement claims against us, and should we be found to infringe upon their patents, or otherwise impermissibly utilize their intellectual property, we might be forced to pay damages, potentially including treble damages, if we are found to have willfully infringed on such parties' patent rights. In addition to any damages we might have to pay, we may be required to obtain licenses from the holders of this intellectual property. We may fail to obtain any of these licenses or intellectual property rights on commercially reasonable terms. Even if we are able to obtain a license, it may be non- exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology. If we are unable to do so, we may be unable to develop or commercialize the affected products, which could materially harm our business and the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and / or other forms of compensation. Conversely, we may not always be able to successfully pursue our claims against others that infringe upon our technology. Thus, the proprietary nature of our technology or technology licensed by us may not provide adequate protection against competitors. **- 36-** In addition to patents, we rely on trademarks to protect the recognition of our company and product in the marketplace. We also rely on trade secrets, know- how, and proprietary knowledge that we seek to protect, in part, through confidentiality agreements with employees, consultants and others. We cannot assure you that our proprietary information will not be shared, our confidentiality agreements will not be breached, that we will have adequate remedies for any breach, or that

our trade secrets will not otherwise become known to or independently developed by competitors. Confidentiality agreements with employees and others may not adequately prevent disclosure of trade secrets and other proprietary information and disclosure of our trade secrets or proprietary information could compromise any competitive advantage that we have, which could have a materially adverse effect on our business. Our success depends, in part, on our ability to protect our proprietary rights to the technologies used in our products and our proprietary clinical treatments. We depend heavily upon confidentiality agreements with our officers, employees, consultants and subcontractors to maintain the proprietary nature of our technology and our proprietary clinical treatments. These measures may not afford us complete or even sufficient protection, and may not afford an adequate remedy in the event of an unauthorized disclosure of confidential information. If we fail to protect and / or maintain our intellectual property, third parties may be able to compete more effectively against us, we may lose our technological or competitive advantage, and / or we may incur substantial litigation costs in our attempts to recover or restrict use of our intellectual property. In addition, others may independently develop technology similar to ours, otherwise avoiding the confidentiality agreements, or produce patents that would materially and adversely affect our business, prospects, financial condition and results of operations in which event and you could lose all of your investment ~~. 37- The United States Federal Trade Commission (FTC) has recently put forward a new policy proposal, currently undergoing public comment and review, that if implemented in its current form, would ban the enforcement of restrictive covenant agreements for employees, thereby making it almost impossible for us to protect our trade secrets and know- how. In that event, we would likely experience a loss of control and confidentiality over our core intellectual property, with unknown consequences~~. We may face intellectual property infringement claims that would be costly to resolve. There has been substantial litigation regarding patent and other intellectual property rights in the medical device industry, and our competitors and others may initiate intellectual property litigation, including as a means of competition. Intellectual property litigation is complex and expensive, and outcomes are difficult to predict. We cannot assure you that we will not become subject to patent infringement claims or litigation, or interference proceedings, to determine the priority of inventions. Litigation or regulatory proceedings also may be necessary to enforce our patent or other intellectual property rights. We may not always have the financial resources to assert patent infringement suits or to defend ourselves from claims. An adverse result in any litigation could subject us to liabilities, or require us to seek licenses from or pay royalties to others that may be substantial. Furthermore, we cannot predict the extent to which the necessary licenses would be available to us on satisfactory terms, if at all. Our failure to secure trademark registrations could adversely affect our ability to market our products and operate our business. Our trademark applications in the United States and any other jurisdictions where we may file may not be allowed registration, and we may not be able to maintain or enforce our registered trademarks. During trademark registration proceedings, we may receive rejections. Although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in corresponding foreign agencies, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our applications and / or registrations, and our applications and / or registrations may not survive such proceedings. Failure to secure such trademark registrations in the United States and in foreign jurisdictions could adversely affect our ability to market our products and our business. **- 37-** We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers. As is common in the medical device industry, we may employ individuals who were previously employed at other companies similar to ours, including our competitors or potential competitors. We may become subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management. We face the risk of product liability claims that could be expensive, divert management' s attention and harm our reputation and business. Our business exposes us to the risk of product liability claims that are inherent in the testing manufacturing and marketing of medical devices. This risk exists even if a device is registered, cleared and approved for commercial sale by the FDA and manufactured in facilities licensed and regulated by the FDA or an applicable foreign regulatory authority. Any side effects, manufacturing defects, misuse or abuse associated with use of our appliance could result in patient injury or death. The medical device industry has historically been subject to extensive litigation over product liability claims, and we cannot offer any assurance that we will not face product liability suits. We may be subject to product liability claims if the use of our appliance may cause, or merely appeared to have caused, patient injury or death. In addition, an injury that is caused by the activities of our suppliers, such as those who provide us with components and raw materials, may be the basis for a claim against us. Product liability claims may be brought against us by patients, healthcare providers or others selling or otherwise coming into contact with our appliances, among others. If we cannot successfully defend ourselves against product liability claims, we will incur substantial liabilities and reputational harm. In addition, regardless of merit or eventual outcome, product liability claims may result in: ● costs of litigation; ~~- 38-~~ ● distraction of management' s attention from our primary business; ● the inability to commercialize our appliances or new products; ● decreased demand and brand reputation for our appliances; ● product recalls or withdrawals from the market; ● withdrawal of clinical trial participants; ● substantial monetary awards to patients or other claimants; or ● loss of sales. Any recall or market withdrawal of our products may delay the supply of those products to our customers and may impact our reputation. We can provide no assurance that we will be successful in initiating appropriate market recall or market withdrawal efforts that may be required in the future or that these efforts will have the intended effect of preventing product malfunctions and the accompanying product liability that may result. Such recalls and withdrawals may also be used by our competitors to harm our reputation for safety or be perceived by patients as a safety risk when considering the use of our products, either of which could have a material adverse effect on our business, financial condition and results of operations. We may not be able to maintain adequate product liability insurance. Our product liability and clinical study liability insurance is subject to deductibles and coverage limitations. Our product liability insurance may not continue to be available to us on acceptable terms, if at all, and, if

available, coverage may not be adequate to protect us against any future product liability claims. If we are unable to obtain insurance at an acceptable cost or on acceptable terms or otherwise protect against potential product liability claims, we could be exposed to significant liabilities. A product liability claim, recall or other claim with respect to uninsured liabilities or for amounts in excess of insured liabilities could have a material adverse effect on our business, financial condition and results of operations. **- 38-** We bear the risk of warranty claims on our appliances. We bear the risk of warranty claims on our appliances. We may not be successful in claiming recovery under any warranty or indemnity provided to us by our suppliers or vendors in the event of a successful warranty claim against us by a customer or that any recovery from such vendor or supplier would be adequate. In addition, warranty claims brought by our customers related to third- party components may arise after our ability to bring corresponding warranty claims against such suppliers expires, which could result in costs to us. Our sales and marketing efforts may not be successful. We currently market and sell our appliances and associated treatments and services to a limited number of licensed professionals, primarily general dentists. Less than 1 % of the general dentists in the U. S. have been trained and certified in The Vivos Method. The commercial success of The Vivos Method ultimately depends upon a number of factors, including the number of dentists who use The Vivos Method, the number of Vivos appliances used by these dentists, the number of patients who become aware of The Vivos Method by self- referral or referrals by their primary care physicians, the number of patients who elect to use The Vivos Method, and the number of patients who, having successfully used The Vivos Method, endorse and refer The Vivos Method to other potential patients. The Vivos Method may not gain significant increased market acceptance among physicians / dentists who use it or who refer their patients, other patients, third- party healthcare insurers and managed care providers. We believe that primary care physicians typically elect to refer individuals to pulmonologists or other physicians who treat sleep disordered breathing, and these physicians may not recommend The Vivos Method to patients for any number of reasons, including safety and clinical efficacy, the availability of alternative procedures and treatment options, or inadequate levels of reimbursement. In addition, while positive patient experiences can be a significant driver of future sales, it is impossible to influence the manner in which this information is transmitted and received, the choices potential patients may make and the recommendations that treating physicians make to their patients. ~~- 39-~~ Although we sell our product directly to our corporate- owned and independent VIP practices, our experience in marketing and selling The Vivos Method or VIP program through a direct sales organization in the United States is limited. We may not be able to maintain a suitable sales force in the United States or train up a suitable number of VIPs, or enter into or maintain satisfactory marketing and distribution arrangements with others. Our marketing and sales efforts may not be successful in increasing awareness and sales of The Vivos Method. In addition, other marketing efforts like MID and our collaborations with Candid **, Ormco** and ~~Empower Sleep~~ **On Demand Orthodontist** may not increase revenue to the extent we currently anticipate. In addition, we conduct our targeted marketing efforts in neighborhoods through channels such as direct mail, billboards, radio advertisements, physician open houses, community sponsorships and various social media. These marketing and sales efforts may not be successful in increasing awareness and sales of The Vivos Method, and if we are not successful in these efforts, we will have incurred expenses without materially increasing revenue. ~~Furthermore, other marketing efforts like MID and the VivoScore Program may not increase revenue to the extent we currently anticipate.~~ The failure to educate or train a sufficient number of physicians and dentists in the use of The Vivos Method could reduce the market acceptance and reduce our revenue. It is critical to the success of our sales efforts that there is an increasing number of dentists familiar with, trained in, and proficient in the use of The Vivos Method. Currently, dentists learn to use The Vivos Method through hands- on, on- site training or virtual training by our representatives. However, to receive this training, dentists must be aware of The Vivos Method as a treatment option for dentofacial abnormalities and / or mild to ~~moderate~~ **severe** OSA and snoring in adults and be interested in using the protocol in their practice. We cannot predict the extent to which dentists will dedicate the time and energy necessary for adequate training in the use of our proprietary treatments, have the knowledge of or experience in the clinical outcomes or feel comfortable enough to recommend it to their patients. Even if a dentist is well versed in The Vivos Method, he or she may be unwilling to require patients to pay for it out- of- pocket. If dentists do not continue to accept and recommend The Vivos Method, our revenue could be materially and adversely affected. **- 39-** We rely on third- party suppliers and contract manufacturers for the manufacture and assembly of our products, and a loss or degradation in performance of these suppliers and contract manufacturers could have a material adverse effect on our business, financial condition and results of operations. We rely on third- party suppliers and contract manufacturers for the raw materials and components used in our appliances and to manufacture and assemble our products. Any of our other suppliers or our third- party contract manufacturers may be unwilling or unable to supply the necessary materials and components or manufacture and assemble our products reliably and at the levels we anticipate or that are required by the market. Our ability to supply our products commercially and to develop any future products depends, in part, on our ability to obtain these materials, components and products in accordance with regulatory requirements and in sufficient quantities for commercialization and clinical testing. While our suppliers and contract manufacturers have generally met our demand for their products and services on a timely basis in the past, we cannot guarantee that they will in the future be able to meet our demand for their products, either because of acts of nature, the nature of our agreements with those manufacturers or our relative importance to them as a customer, and our manufacturers may decide in the future to discontinue or reduce the level of business they conduct with us. If we are required to change contract manufacturers due to any change in or termination of our relationships with these third parties, or if our manufacturers are unable to obtain the materials they need to produce our products at consistent prices or at all, we may lose sales, experience manufacturing or other delays, incur increased costs or otherwise experience impairment to our customer relationships. We cannot guarantee that we will be able to establish alternative relationships on similar terms, without delay or at all. ~~- 40-~~ Establishing additional or replacement suppliers for any of these materials, components or services, if required, could be time- consuming and expensive, may result in interruptions in our operations and product delivery, may affect the performance specifications of our appliances or could require that we modify its design. Even if we are able to find replacement suppliers or third- party contract

manufacturers, we will be required to verify that the new supplier or third- party manufacturer maintains facilities, procedures and operations that comply with our quality expectations and applicable regulatory requirements. If our third- party suppliers fail to deliver the required commercial quantities of materials on a timely basis and at commercially reasonable prices, and we are unable to find one or more replacement suppliers capable of production at a substantially equivalent cost in substantially equivalent volumes and quality on a timely basis, the continued commercialization of our appliances, the supply of our products to customers and the development of any future products will be delayed, limited or prevented, which could have material adverse effect on our business, financial condition and results of operations. Damage to our reputation or our brand could negatively impact our business, financial condition, and results of operations. We must grow the value of our brand to be successful. We intend to develop a reputation based on the high quality of our products and services, Vivos trained clinicians, as well as on our particular culture and the experience of the patients of our VIPs. If we do not make investments in areas such as marketing and advertising, as well as personnel training, the value of our brand may not increase or may be diminished. Any incident, real or perceived, regardless of merit or outcome, that adversely affects our brand, such as, but not limited to, patient disability or death due to malpractice or allegations of malpractice, failure to comply with federal, state, or local regulations, including allegations or perceptions of non- compliance or failure to comply with ethical and operational standards, could significantly reduce the value of our brand, expose us to negative publicity and damage our overall business and reputation. Our marketing activities may not be successful. We incur costs and expend other resources in our marketing efforts to attract and retain VIPs and other medical professionals. Our marketing activities **are** ~~to date have had limited impact in terms of overall market penetration, and have been~~ principally focused on increasing brand awareness in the communities in which we provide services. We expect to continue to undertake aggressive marketing campaigns to increase medical and dental community awareness about our product and service capabilities. We conduct our marketing efforts in **neighborhoods** ~~local areas primarily~~ through **channels such as direct mail, billboards, radio advertisements, physician open houses, community sponsorships and** various social media ~~and online channels, radio advertisements, physician referrals, other professional referrals, and community event sponsorships~~ . If we are not successful in these efforts, we will have incurred expenses without materially increasing revenue. **- 40-** The OSA market is highly competitive, including competition for patients, strategic relationships, and commercial payor contracts. The market for providing treatment for OSA is highly competitive. Our VIP offices and our VIPs face competition from existing facilities providing treatment for OSA, depending on the type of patient and geographic market. Our VIPs compete on the basis of our protocol / products (The Vivos Method), quality, price, accessibility, and overall experience. We compete with national, regional, and local enterprises, many of which have greater financial and other resources available to them, greater access to dentists and physicians or greater access to potential patients. We also compete on the basis of our multistate, regional footprint, which we believe will be of value to both employers and third- party payors. As a result of the differing competitive factors within the markets in which we operate and will operate, the individual results of our VIP offices may be volatile. If we are unable to compete effectively with any of these entities or groups, or we are unable to implement our business strategies, there could be a material adverse effect on our business, prospects, results of operations and financial condition. ~~- 41-~~ We have limited clinical evidence to support patient compliance with the use our products is superior to competitive products. We believe that our non- surgical treatment of limited duration is preferable relative to mild to ~~moderate~~ **severe** OSA CPAP users or other oral appliance or surgical therapies, resulting in improved patient compliance. However, we have limited clinical evidence to support our beliefs that patient compliance in the use of our products **is** ~~as well as actual clinical outcomes are~~ superior to competitive products. If actual patient compliance as studied in a clinical trial (should we conduct one) proves less than what we had anticipated, the acceptance of The Vivos Method in the marketplace, and our revenues and overall results of operations, may be adversely impacted. Government healthcare programs may reduce reimbursement rates, which could adversely affect sales of our appliances and demand for dental practitioners from becoming or remaining VIPs. In recent years, new legislation has been proposed and adopted at both the federal and state level that is effecting major changes in the healthcare system. Any change in the laws, regulations, or policies governing the healthcare system could adversely affect reimbursement rates, which could adversely affect sales of our appliances and thus adversely affect our operations and financial condition. Enacted in 2010, the Affordable Care Act (or ACA) seeks to expand healthcare coverage, while increasing quality and limiting costs. The ACA substantially changes the way healthcare is financed by both governmental and commercial payors. As a result of the ACA or the adoption of additional federal and state healthcare reforms measures there could be limits to the amounts that federal and state governments will pay for healthcare services, which could result in reduced demand for, or profitability of our appliances and for dental practitioners from becoming or remaining VIPs. Significant uncertainty exists as to the reimbursement status of healthcare products. The regulations that govern marketing approvals, pricing and reimbursement for medical devices vary widely from country to country. In the United States, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act of 2010, is significantly changing the way healthcare is financed by both governmental and private insurers. While we cannot predict what impact on federal reimbursement policies this law or any amendment to it will continue to have in general or specifically on The Vivos Method or any product that we commercialize, the ACA or any such amendment may result in downward pressure on reimbursements, which could negatively affect market acceptance of The Vivos Method. In addition, although the United States Supreme Court has upheld the constitutionality of most of the ACA, several states have not implemented certain sections of the ACA, including 19 that have rejected the expansion of Medicaid eligibility for low- income citizens, and some members of the U. S. Congress are still working to repeal the ACA. We expect that the ACA, as currently enacted or as it may be amended or repealed in the future, and other healthcare reform measures that may be adopted in the future, could have a material adverse effect on our industry generally and on our ability to successfully commercialize our products. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or

policies, or if we or our collaborators are not able to maintain regulatory compliance, our products may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability, which would adversely affect our business. - 41- If payments from commercial or governmental payors are significantly delayed, reduced or eliminated, our business, prospects, results of operations and financial condition could be adversely affected. We will depend upon revenue from sales of the billable procedures from The Vivos Method, and in turn on reimbursement from third- party payors. The amount that our VIPs receive in payment for the billable procedures may be adversely affected by factors we do not control, including federal or state regulatory or legislative changes, cost- containment decisions and changes in reimbursement schedules of third- party payors. Any reduction or elimination of these reimbursements could have a material adverse effect on our business, prospects, results of operations and financial condition. Additionally, the reimbursement process is complex and can involve lengthy delays. Also, third- party payors may reject, in whole or in part, requests for reimbursement based on determinations that certain amounts are not reimbursable under plan coverage, that services provided were not medically necessary, that additional supporting documentation is necessary, or for other reasons. Retroactive adjustments by third- party payors may be difficult or cost prohibitive to appeal, and such changes could materially reduce the actual amount we receive from our VIPs. Delays and uncertainties in the reimbursement process may be out of our control and may adversely affect our business, prospects, results of operations and financial condition. ~~- 42-~~Significant changes in our payor mix resulting from fluctuations in the types of patients seen by our VIPs could have a material adverse effect on our business, prospects, results of operations and financial condition. Our results may change from period to period due to fluctuations in our VIPs' payor mix. Payor mix refers to the relative amounts we receive from the mix of persons or entities that pay or reimburse our VIPs for healthcare services. Because we believe that our VIPs will receive a higher payment rate from commercial payors than from governmental payors or self- pay patients, a significant shift in our payor mix toward a higher percentage of self- pay or patients whose treatment is paid in whole or part by a governmental payor, could occur for reasons beyond our control and could lessen demand for The Vivos Method, which in turn could have a material adverse effect on our business, prospects, results of operations and financial condition. Failure by our Billing Intelligence Service to bill timely or accurately for billable services rendered by participating VIP providers could have a negative impact on our revenue and cash flow. Billing for medical services rendered in connection with billable procedures of The Vivos Method is often complex and time consuming. The practice of providing dental or medical services in advance of payment or prior to assessing a patient' s ability to pay for such services may have a significant negative impact on a VIP provider' s patient service revenue, bad debt expense and cash flow. Not all our VIPs subscribe to our Billing Intelligence Service. For VIPs who do subscribe, we bill numerous medical payors, including various forms of commercial health insurance providers on their behalf. Billing requirements that must be met prior to receiving payment for services rendered often vary by payor. Self- pay patients and third- party payors may fail to pay for services even if they have been properly billed. Reimbursement is typically dependent on providing the proper procedure and diagnosis codes, supportive documentation to show medical necessity. Medical insurance is never a guarantee of payment. Additional factors that could affect our ability to collect from insurers for the services rendered by our participating VIP providers include: ● disputes among payors as to which party is responsible for payment; ● variations in coverage among various payors for similar services; ● the difficulty of adherence to specific compliance requirements, coding and various other procedures mandated by responsible parties; ● the institution of new coding standards; and ● failure to properly credential a dentist to enable them to bill various payors. The complexity associated with billing for The Vivos Method procedures may lead to delays in cash collections by our VIPs, resulting in increased carrying costs associated with the aging of our accounts receivable as well as the increased potential for bad debt expense. - 42- We may incur costs resulting from security risks in connection with the electronic data processing by our partner banks. Because we accept electronic payment cards for payments at our facilities and the facilities of our VIPs, we may incur costs resulting from related security risks in connection with the electronic processing of confidential information by our partner banks. Recently, several large national banks have experienced potential or actual breaches in which similar data has been or may have been stolen. Such occurrences could cause patient dissatisfaction resulting in decreased visits or could also distract our management team from the management of the day- to- day operations. Our relationships with VIPs, other healthcare providers, and third- party payors will 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 healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties. Healthcare providers (including our VIPs), physicians and third- party payors in the United States and elsewhere will play a primary role in the recommendation of The Vivos Method. Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third- party payors may subject us to various federal and state fraud and abuse laws and other health care laws, including, without limitation, the federal Anti- Kickback Statute, the federal civil and criminal false claims laws and the law commonly referred to as the Physician Payments Sunshine Act and regulations. These laws will impact, among other things, our clinical research, sales, marketing and educational programs. In addition, we may be subject to patient privacy laws by both the federal government and the states in which we conduct or may conduct our business. The laws that will affect our operations 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, in return for the purchase, recommendation, leasing or furnishing of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs. This statute has been interpreted to apply to arrangements between medical device manufacturers on the one hand, and physicians and patients on the other. The Patient Protection and Affordable Care Act, as amended (or the PPACA), amended the intent requirement of the federal Anti- Kickback Statute and, as a result, a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it; ~~- 43-~~● federal civil and criminal false claims laws, including, without limitation, the False Claims Act, and civil monetary penalty laws which prohibit, among

other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid or other government payors that are false or fraudulent or making a false statement to ~~avoid~~ **Avoid**, decrease or conceal an obligation to pay money to the federal government. The PPACA provides, and recent government cases against medical device manufacturers support, the view that federal Anti- Kickback Statute violations and certain marketing practices, including off- label promotion, may implicate the False Claims Act; ● the federal Health Insurance Portability and Accountability Act of 1996 (~~"~~ **or** HIPAA ~~"~~), which created new federal criminal statutes that prohibit a person from knowingly and willfully executing a scheme or making false or fraudulent statements to defraud any healthcare benefit program, regardless of the payor (e. g., public or private); ● HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (~~"~~ **or** HITECH ~~"~~), and its implementing regulations, and as amended again by the final HIPAA omnibus Rule, Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules Under HITECH and the Genetic Information Nondiscrimination Act; Other Modifications to HIPAA, published in January 2013, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization by entities subject to the rule, such as health plans, health care clearinghouses and health care providers, and their respective business associates; **- 43-** ● Federal transparency laws, including the federal Physician Payments Sunshine Act, which is part of the PPACA, that require certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children' s Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services (or CMS), information related to: (i) payments or other " transfers of value **"** ~~''~~ made to physicians and teaching hospitals; and (ii) ownership and investment interests held by physicians and their immediate family members; ● state and foreign law equivalents of each of the above federal laws, state laws that require manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures, and state laws that require medical device companies to comply with the specific industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or to adopt compliance programs as prescribed by state laws and regulations, or that otherwise restrict payments that may be made to healthcare providers; and ~~- 44-~~ ● state and foreign laws that 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. 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 under one or more of such laws. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion of our products from government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non- compliance with these laws and the curtailment or restructuring of our operations. The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management' s attention from the operation of our business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and / or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements. The misuse or off- label use of The Vivos Method 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. We train our marketing personnel and direct sales force to not promote the oral appliances of The Vivos Method for uses outside of the FDA- cleared indications for use, known as off- label uses. We cannot, however, prevent a medical professional from using our appliances off label when, in their independent professional medical judgment, he or she deems it appropriate. There may be increased risk of injury or other side effects to patients if physicians attempt to use our appliances and associated treatments off label. Furthermore, the use of our appliances and associated treatments for indications other than those cleared by the FDA or cleared by any foreign regulatory body may not effectively treat such conditions, which could harm our reputation in the marketplace among physicians and patients. **- 44-** Given that we are aware that, notwithstanding our training guidelines, our independent VIPs may use our appliances off- label, there is a risk that we could face regulatory scrutiny because of such use. If the FDA or any foreign regulatory body determines that our promotional (labeling) materials or training constitute promotion of an off- label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance or imposition of an untitled letter, which is used for violations that do not necessitate a 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, such as false claims laws, if they consider our business activities to constitute promotion of an off- label use, which could result in significant penalties, including, but not limited to, criminal, civil and administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs and the curtailment of our operations. In addition, dentists may misuse our appliances within The Vivos Method or use improper techniques if they are not adequately trained ~~or if they deviate in their techniques or protocols from those we promulgate and endorse~~, potentially leading to injury and an increased risk of product liability. If The Vivos Method is misused or used with improper technique, we may become subject to costly litigation by our customers or their patients. Similarly, in an effort to decrease costs, physicians may also reuse our appliances despite

them being intended for a single use or may purchase reprocessed Vivos appliances from third- party processors in lieu of purchasing a new Vivos appliance from one of our contract manufacturers, which could result in product failure and liability. 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. ~~- 45- It is also possible that alternative products available in the market that make claims similar to ours may cause confusion or the impression that such products are substantially the same, or work in substantially the same manner as our products, or that they have similar regulatory approvals or are backed by clinical research. If that were to occur, the company may lose market share or be unfairly lumped into any regulatory or legal actions that may arise from such third- party claims.~~ We have ~~undertaken~~ **engaged in** and **may** ~~plan to~~ continue to ~~explore~~ **pursue** acquisitions of complementary businesses or technologies, which could divert the attention of management, and which may not be integrated successfully into our existing business. We have ~~undertaken~~ **engaged in** and **may** ~~plan to~~ continue to ~~explore~~ **pursue** acquisitions or licenses of technology to, among other things, expand the scope of products **and** services we provide. **For** ~~Examples~~ **example , in** ~~of our implementation of this strategy include our (i) late~~ February 2023 ~~acquisition of~~ **, acquired** certain U. S. and international patents, product rights, and other miscellaneous intellectual property from Advanced Facialdontics, LLC ~~, (ii) March 2021 acquisition certain assets related to our OMT service in March 2021 from MyoCorrect, LLC, and (iii) April 2021 acquisition of certain medical billing and practice management software, licenses and contracts (including the software underlying AireO2) from Lyon Management and Consulting, LLC~~. **We** ~~The acquisition and integration of another business or technology can divert management attention from other business activities, including our core business. This diversion, together with other difficulties we may incur in integrating an acquired business or technology, could have a material adverse effect on our business, financial condition and results of operations. As for future potential acquisitions, we~~ cannot guarantee that we will identify suitable acquisition candidates, that acquisitions will be completed on acceptable terms or that we will be able to successfully integrate the operations of any acquired business into our existing business. The acquisitions could be of significant size and involve operations in multiple jurisdictions **. The acquisition and integration of another business or technology would divert management attention from other business activities, including our core business. This diversion, together with other difficulties we may incur in integrating an acquired business or technology, could have a material adverse effect on our business, financial condition and results of operations** . In addition, we may borrow money or issue capital stock to finance acquisitions. Such borrowings might not be available on terms as favorable to us as our current borrowing terms and may increase our leverage, and the issuance of capital stock could dilute the interests of our stockholders. Our business is seasonal, which impacts our results of operations ~~. Historically, our fourth quarters tend to be our best performing quarters, both in terms of new VIP enrollments as well as appliance sales from case starts, while the first quarters have tended to be our worst~~ . We believe that the patient volumes of our VIPs will be sensitive to seasonal fluctuations in urgent care and primary care activity. Typically, winter months see a higher occurrence of influenza, bronchitis, pneumonia and similar illnesses; however, the timing and severity of these outbreaks vary dramatically. Additionally, as consumers shift toward high deductible insurance plans, they are responsible for a greater percentage of their bill, particularly in the early months of the year before other healthcare spending has occurred, which may lead to lower than expected patient volume or an increase in bad debt expense during that period. Our quarterly operating results may fluctuate significantly in the future depending on these and other factors. We could be subject to lawsuits for which we are not fully insured. Healthcare providers have become subject to an increasing number of lawsuits alleging malpractice and related legal theories such as negligent hiring, supervision and credentialing. Some of these lawsuits involve large claim amounts and substantial defense costs. We generally procure professional liability insurance coverage for our affiliated medical professionals and professional and corporate entities. We are currently insured under policies in amounts management deems appropriate, based upon the nature and risk of our business. Our medical professionals are also required to provide their own medical malpractice insurance coverages. Nevertheless, there are exclusions and exceptions to coverage under each insurance policy that may make coverage for any claim unavailable, future claims could exceed the limits of available insurance coverage, existing insurers could become insolvent and fail to meet their obligations to provide coverage for such claims, and such coverage may not always be available with sufficient limits and at reasonable cost to insure us adequately and economically in the future. One or more successful claims against us not covered by, or exceeding the coverage of, our insurance could have a material adverse effect on our business, prospects, results of operations and financial condition. Moreover, in the normal course of our business, we may be involved in other types of lawsuits, claims, audits and investigations, including those arising out of our billing and marketing practices, employment disputes, contractual claims and other business disputes for which we may have no insurance coverage. Furthermore, for our losses that are insured or reinsured through commercial insurance providers, we are subject to the financial viability of those insurance companies. Although we believe our commercial insurance providers are currently creditworthy, they may not remain so in the future. The outcome of these matters could have a material adverse effect on our financial position, results of operations, and cash flows.- ~~46~~ **45** - We depend on certain key personnel. We substantially rely on the efforts of our current senior management, including our Chief Executive Officer, R. Kirk Huntsman, our Chief Financial Officer, Brad Amman ~~,~~ **and** Susan McCullough, our EVP of Operations ~~, and Patrick Kircher, our EVP of Sales and Marketing~~ , among others. Our business would be impeded or harmed if we were to lose their services. In addition, if we are unable to attract, train and retain highly skilled technical, managerial, product development, sales and marketing personnel, we may be at a competitive disadvantage and unable to develop new products or increase revenue. The failure to attract, train, retain and effectively manage employees could negatively impact our research and development, sales and marketing and reimbursement efforts. In particular, the loss of sales personnel could lead to lost sales opportunities as it can take several months to hire and train replacement sales personnel. Uncertainty created by turnover of key employees could adversely affect our business. Members of our ~~Board~~ **board** of ~~Directors~~ **directors** and our executive officers will have other business interests and obligations to other entities. Neither our directors nor our executive officers will be required to manage our business as their sole and

exclusive function and they may have other business interests and may engage in other activities in addition to those relating to us, provided that such activities do not compete with the business of our company or otherwise breach their agreements with us. We are dependent on our directors and executive officers to successfully operate our company. Their other business interests and activities could divert time and attention from operating our business. We will need to carefully manage our expanding operations to achieve sustainable growth. To achieve increased revenue levels, complete clinical studies and develop future products, we believe that we will be required to periodically expand our operations, particularly in the areas of sales and marketing, clinical research, reimbursement, research and development, manufacturing and quality assurance. As we expand our operations in these areas, management will face new and increased responsibilities. To accommodate any growth and compete effectively, we must continue to upgrade and improve our information systems, as well as our procedures and controls across our business, and expand, train, motivate and manage our work force. Our future success will depend significantly on the ability of our current and future management to operate effectively. Our personnel, systems, procedures and controls may not be adequate to support our future operations. If we are unable to effectively manage our expected growth, this could have a material adverse effect on our business, financial condition and results of operations. We could be adversely affected by violations of the U. S. Foreign Corrupt Practices Act and similar worldwide anti- bribery and anti- kickback laws with respect to our activities outside the United States. We distribute our products to locations within and outside the United States and Canada. Our business plan also anticipates VIP offices outside the United States and Canada. The U. S. Foreign Corrupt Practices Act, and other similar anti- bribery and anti- kickback laws and regulations, generally prohibit companies and their intermediaries from making improper payments to non- U. S. officials for the purpose of obtaining or retaining business. As we expect to expand our international operations in the future, we will become increasingly subjected to these laws and regulations. We cannot assure you that we will be successful in preventing our agents from taking actions in violation of these laws or regulations. Such violations, or allegations of such violations, could disrupt our business and result in a material adverse effect on our financial condition, results of operations and cash flows. **- 46-** Risks Related to Our Products and Regulation We depend in large part on The Vivos Method technology, and the loss of access to this technology would terminate or delay the further development of our products, injure our reputation or force us to pay higher fees. We depend, in large part, on The Vivos Method technology. The loss ~~or dilution~~ of ~~the trade secrets and other intellectual property that comprises~~ this key technology would seriously impair our business and future viability, and could result in delays in developing, introducing or maintaining our treatments / products until equivalent technology, if available, is identified, licensed and integrated. In addition, any defects in the products of The Vivos Method technology or other technologies we gain access to in the future could prevent the implementation or impair the functionality of our products, delay new product introductions or injure our reputation. If we are required to acquire or enter into license agreements with third parties for replacement technologies, we could be subject to higher fees, milestone or royalty payments, assuming we could access such technologies at all. ~~- 47 -~~ Our failure to obtain government approvals, including required FDA approvals, or to comply with ongoing, and ever increasing, governmental regulations relating to our technologies and products could delay or limit introduction of our products and result in failure to achieve revenue or maintain our ongoing business. Our development activities and the manufacture and marketing of The Vivos Method are subject to extensive regulation for safety, efficacy and quality by numerous government authorities in the United States and abroad. Before receiving FDA or foreign regulatory clearance to market our future products needing approval, we will have to demonstrate that these products are safe and effective in the patient population and for the diseases that are to be treated. Clinical trials, manufacturing and marketing of medical devices are subject to the rigorous testing and approval process of the FDA and equivalent foreign regulatory authorities. The Federal Food, Drug and Cosmetic Act and other federal, state and foreign statutes and regulations govern and influence the testing, manufacture, labeling, advertising, distribution and promotion of medical devices. As a result, regulatory approvals for our products not yet approved or that we may develop in the future can take a number of years or longer to accomplish and require the expenditure of substantial financial, managerial and other resources. Clinical trials that may be required to support regulatory submissions in the United States are expensive. We cannot assure that we will be able to complete any required clinical trial programs successfully within any specific time period, and if such clinical trials take longer to complete than we project, our ability to execute our current business strategy will be adversely affected. Conducting clinical trials is a lengthy, time- consuming and expensive process. Before obtaining regulatory approvals for the commercial sale of any products, we must demonstrate through clinical trials the safety and effectiveness of our products. We have incurred, and we will continue to incur, substantial expense for, and devote a significant amount of time to, product development, pilot trial testing, clinical trials and regulated, compliant manufacturing processes. Even if completed, we do not know if these trials will produce statistically significant or clinically meaningful results sufficient to support an application for marketing approval. If and how quickly we complete clinical trials is dependent in part upon the rate at which we are able to advance the rate of patient enrollment, and the rate to collect, clean, lock and analyze the clinical trial database. Patient enrollment in trials is a function of many factors. These include the design of the protocol; the size of the patient population; the proximity of patients to and availability of clinical sites; the eligibility criteria for the study; the perceived risks and benefits of the product candidate under study; the medical investigators' efforts to facilitate timely enrollment in clinical trials; the patient referral practices of local physicians; the existence of competitive clinical trials; and whether other investigational, existing or new products are available or cleared for the indication. If we experience delays in patient enrollment and / or completion of our clinical trial programs, we may incur additional costs and delays in our development programs and may not be able to complete our clinical trials on a cost- effective or timely basis. Accordingly, we may not be able to complete the clinical trials within an acceptable time frame, if at all. If we fail to enroll and maintain the number of patients for which the clinical trial was designed, the statistical power of that clinical trial may be reduced, which would make it harder to demonstrate that the product candidate being tested in such clinical trial is safe and effective. Further, if we or any third party have difficulty enrolling a sufficient number of patients in a timely or cost- effective manner to conduct clinical trials as planned, or if enrolled patients do not

complete the trial as planned, we or a third party may need to delay or terminate ongoing clinical trials, which could negatively affect our business.- ~~48~~ **47** - The results of our clinical trials may not support either further clinical development or the commercialization of any new product candidates or modifications to existing products. Even if our ongoing or contemplated clinical trials are completed as planned, their results may not support either the further clinical development or the commercialization of any new product candidates or modifications of existing products. The FDA or government authorities may not agree with our conclusions regarding the results of our clinical trials. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and the results from any later clinical trials may not replicate the results of prior clinical trials and pre- clinical testing. The clinical trial process may fail to demonstrate that our product candidates are safe and effective for indicated uses. This failure would cause us to abandon a product candidate or a modification to any existing product and may delay development of other product candidates. Any delay in, or termination of, our clinical trials will delay the filing of our 510 (k)' s and, ultimately, our ability to commercialize our product candidates and generate product revenue. Generally, Class II medical device marketed in the U. S. must receive a 510 (k) clearance from the FDA. A 510 (k) is a premarket submission made to FDA to demonstrate that the device to be marketed is at least as safe and effective, that is, substantially equivalent (or SE), to a legally marketed device. Companies must compare their device to one or more similar legally marketed devices, commonly known as " predicates ", and make and support their substantial equivalency claims. The submitting company may not proceed with product marketing until it receives an order from the FDA declaring a device substantially equivalent. The substantially equivalent determination is usually made within 90 days, based on the information submitted by the applicant. In addition, we or the FDA may suspend our clinical trials at any time if it appears that we are exposing participants to unacceptable health risks or if the FDA finds deficiencies in the conduct of these trials. A number of companies in the medical technology industry have suffered significant setbacks in advanced clinical trials despite promising results in earlier trials. In the end, we may be unable to develop marketable products. Modifications to appliances within The Vivos Method may require additional FDA approvals which, if not obtained, could force us to cease marketing and / or recall the modified device until we obtain new approvals. After a device receives a 510 (k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new 510 (k) clearance or could require a Premarket approval (or PMA). PMA is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury. Currently we do not market devices within this Class III category nor do we intend to in the foreseeable future. However, the FDA requires each manufacturer to make this determination in the first instance, but the FDA can review any decision. If the FDA disagrees with a manufacturer' s decision not to seek a new 510 (k) clearance, the agency may retroactively require the manufacturer to seek 510 (k) clearance or PMA approval. The FDA also can require the manufacturer to cease marketing and / or recall the modified devices until 510 (k) clearance or PMA approval is obtained. We cannot assure you that the FDA would agree with any of our decisions not to seek 510 (k) clearance or PMA approval. If the FDA requires us to seek 510 (k) clearance or PMA approval for any modification, we also may be required to cease marketing and / or recall the modified device until we obtain a new 510 (k) clearance or PMA approval. We are subject to inspection and market surveillance by the FDA to determine compliance with regulatory requirements. If the FDA finds that we have failed to comply, the agency can institute a wide variety of enforcement actions which may materially affect our business operations. We are subject to inspection and market surveillance by the FDA to determine compliance with regulatory requirements. If the FDA finds that we have failed to comply, the agency can institute a wide variety of enforcement actions, ranging from a public warning letter to more severe sanctions such as: ● fines, injunctions and civil penalties; **- 48-** ● recall, detention or seizure of our products; ● the issuance of public notices or warnings; ● operating restrictions, partial suspension or total shutdown of production; ● refusing our requests for a 510 (k) clearance of new products or new uses of existing products; ● withdrawing a 510 (k) clearance already granted; and ● criminal prosecution. ~~- 49-~~ We have received an FDA warning letter in the past when such a letter was received by our subsidiary BioModeling Solutions, Inc. (" BioModeling " or " BMS ") in January 2018 following a routine FDA audit. In its letter, the FDA noted matters such as inadequate documentation of certain FDA- required procedures, not keeping certain records and materials in paper format and in triplicate, and using certain descriptive words and phrases on its website and in marketing materials that were unapproved in advance by FDA. **We believe** ~~On January 31, 2023, the~~ **these issues have been resolved as of our latest** FDA ~~sent us a letter stating that, based on~~ **audit in fall of 2022 by not having any repeat offenses from** ~~their~~ -- **the stated observations of said** ~~evaluation, the violations contained in~~ warning letter ~~were addressed,~~ and ~~therefore~~ **we have submitted written request to have** the warning letter **resolved** ~~was considered closed- out. Future FDA inspections and regulatory activities will further assess the adequacy and sustainability of those corrections, and we may again become subject to FDA review and scrutiny, which could adversely impact our business~~ . The FDA also has the authority to request repair, replacement or refund of the cost of any medical device manufactured or distributed by us. Our failure to comply with applicable requirements could lead to an enforcement action that may have an adverse effect on our financial condition and results of operations. Treatment with The Vivos Method has only been available for a relatively limited time, and we do not know whether there will be significant post- treatment regression or relapse. Patient treatment using the FDA registered DNA appliance began in 2009, while treatment for mild to moderate OSA using the FDA cleared mRNA appliance began in 2014. Both began under the prior business model of our predecessor (and now subsidiary) BMS, and well before our formation. Under the BMS model, the independent treating dentists generated and maintained all records of treatment and ordered their appliances directly from one of the BMS designated labs. Thus, with the exception of specific patients who participated in studies, clinical trials or case reports, we have had limited visibility into patient records which might contain data on **this subject** ~~the long- term durability and stability of our treatment beyond just a few years~~ . Therefore, we have limited empirical data to support our view that the risk of post treatment regression or relapse is not significant. To the extent a material number of patients who were

treated with The Vivos Method were to be found to experience post- treatment relapse or regression, it could pose a significant risk to our brand, the willingness or ability of physicians to prescribe and dentists to use our products and the willingness of patients to engage in treatment with our products and could thus have a material adverse effect on our results of operations. We are subject to potential risks associated with the need to comply with state or other DSO laws. Our core VIP business model does not involve any form of joint ownership, operational control, or employment of licensed professionals by our company. Thus, we are not typically regarded as a " dental service organization " (or DSO) under the laws of the various states within the United States or in Canada, in which we conduct most of our business. However, we do operate two retail treatment clinics in Colorado wherein we do employ dentists under a provider network model consistent with Colorado law. In that respect, we may be regarded as a DSO. In addition, we have begun to strategically establish a nationwide network of professional corporations, owned by independent licensed dentists in each state, in order to lay the regulatory groundwork for our Airway Alliance model and program. In essence, Airway Alliance will operate in similar fashion to a DSO, thus providing us with what we believe to be certain strategic and competitive advantages. Nevertheless, to the extent we are deemed to be a DSO in any jurisdiction, it could make it difficult or impossible for us to recruit and retain qualified dentists as VIPs, as some state dental boards are sometimes adverse to corporate DSOs operating in their states. Moreover, where such DSO- provider relationships are permitted, such regulations may impose significant constraints on the structure and financial arrangements that are permissible between us and our affiliated dentists in a particular state. In jurisdictions where laws allow DSOs to operate (which includes almost all U. S. states and Canada), a growing number of dentists are affiliating with corporate DSOs. In those cases, the DSO may not allow their affiliated dentists to offer our products and services or to become VIPs. Thus, the overall number of dentists who are prospects to become VIPs and utilize our products and services may be reduced, which would impair our ability to generate revenue from our core VIP business model. **- 49-** Our Medical Integration Division business line may implicate federal and state laws involving the practice of medicine and related anti- kickback and similar laws. Our MID was launched in 2020 to assist VIP practices in establishing clinical collaboration ties to local primary care physicians, sleep specialists, ENTs, pediatricians and other healthcare professionals who routinely see or treat patients with sleep and breathing disorders. The primary objective of our MID is to promote The Vivos Method to the medical profession and thus facilitate more patients being able to receive a treatment with The Vivos Method. There is a risk, however, that our MID may implicate legal or regulatory compliance issues that may arise in the course of our activities, including various Federal healthcare statutes such as the Stark and anti- kickback laws as well as state- by- state regulations pertaining to inter- disciplinary ownership of professional corporations or other legal entities. We have conducted research, including obtaining advice from outside legal counsel, regarding the implications of these laws and regulations to MID and believe the MID' s operations will be in compliance with or will not implicate these laws and regulations. However, there is a risk that such laws and regulations (or similar laws and regulations adopted in the future) might be interpreted, reinterpreted, or modified in the future in such a way so as to impede or prevent us from continuing to develop or manage our MID, which could lead to our having to discontinue the MID and could leave us subject to regulatory scrutiny and sanction. No advice of counsel has been obtained with respect any potential operations of the MID in Canada. ~~- 50-~~ We may not be able to prohibit or limit our dentists, physicians and other healthcare professionals from competing with us in our local markets. In certain states in which we operate or intend to operate, non- compete, non- solicitation, and other negative covenants applicable to employment or ownership are judicially or statutorily limited in their effectiveness or are entirely unenforceable against dentists, physicians and other healthcare professionals. As a result, we may not be able to retain our provider relationships or protect our market share, operational processes or procedures, or limit insiders or VIPs from using competitive information against us or competing with us, which could have a material adverse effect on our business, financial condition and ability to remain competitive as our arrangements with our VIPs do not contain competitive restrictions. Risks Related to Our Securities Generally The market for our common stock is relatively new and may not develop to provide investors with adequate liquidity. We conducted our initial public offering in December 2020, and a follow- on offering in May 2021. Therefore, the market for our common stock is relatively new, and has ~~experience~~ **experienced** periods of inactivity as well as significant volatility. We cannot assure you that an orderly and liquid trading market for our common stock will develop, or if it does develop, it may not be maintained. You may not be able to sell your common stock quickly or at the market price if trading in our securities is not active. The market price of our common stock has been and may continue to be highly volatile, **and you could** ~~which creates the risk of substantial losses~~ **lose all** ~~for~~ **or** ~~investors~~ **part of your investment** . The market price of our common stock has ~~at times~~ been, and is likely in the future to be, volatile **(which we define the frequency and magnitude of movements in the market price for our common stock). As we believe is typical for smaller public companies, particularly those who operate in our industry, our common stock prices have been volatile around the times we announce significant news to the marketplace or when we conduct financings. For example, in late November 2023, we announced that our CARE appliances were cleared by the FDA to treat moderate and severe OSA in adults, 18 years of age and older along with positive airway pressure (PAP) and / or myofunctional therapy, as needed** . This **announcement was followed by an over 800 % increase in the price of our common stock with over 46 million shares of common stock traded on November 29, 2023. There is a significant risk that this level of upward market volatility will not be sustained, and downward volatility in our public stock price could lead to investment losses by our stockholders. It is important to note that market volatility is not something over which we have direct control.- 50- Moreover,** volatility may prevent you from being able to sell your securities at or above the price you paid for your securities. Our stock price could be subject to wide fluctuations in response to a variety of factors, which include: ● whether we achieve our anticipated corporate objectives; ● actual or anticipated fluctuations in our quarterly or annual operating results; ● changes in our financial or operational estimates or projections; ● our ability to implement our operational plans; ● restrictions on the ability of our stockholders to sell shares in the future; ● changes in the economic performance or market valuations of companies similar to ours; and ● general economic or political conditions in the United States or elsewhere. In addition, the stock market in general, and the stock of publicly-

traded medical technology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance **, and downward volatility in our public stock price could lead to investment losses by our stockholders** . ~~- 51- Our~~ **We are presently subject to potential delisting from Nasdaq, and our** failure to meet **and maintain** the continuing listing requirements of The Nasdaq Capital Market could result in a ~~de- listing~~ **delisting** of our securities. If we fail to satisfy the continuing listing requirements of Nasdaq, such as the corporate governance, stockholders equity or minimum closing bid price requirements, Nasdaq may take steps to delist our common stock. Such a delisting would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. In the event of a delisting, we would likely take actions to restore our compliance with Nasdaq' s listing requirements, but we can provide no assurance that any such action taken by us would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our securities, prevent our common stock from dropping below the Nasdaq minimum bid price requirement or prevent future non- compliance with Nasdaq' s listing requirements. During 2022, we received two notices from Nasdaq informing us of our failure to comply with two continuing Nasdaq listing requirements: failure to timely file our reports with the SEC, and failure to achieve the Nasdaq minimum bid price for 30 consecutive trading days. While both of these deficiencies were cleared by January 2023, we ~~may again become~~ **became** subject to ~~potential~~ **additional** delisting from Nasdaq **during 2023, one for failure to meet the minimum bid requirement and the other for failing to meet Nasdaq' s $ 2. 5 million minimum stockholders' equity requirement. On September 21, 2023, we received a written notice from the Nasdaq staff confirming that since, as of that date, we failed to meet the minimum bid price requirement, and because as of the period ended June 30, 2023 we also failed the minimum stockholders' equity requirement, Nasdaq would commence delisting proceedings against us. As permitted under Nasdaq rules, we appealed the Nasdaq staff' s determination and requested a hearing (the " Hearing ") before a Nasdaq Hearing Panel (the " Hearing Panel "). The Hearing request stayed any delisting or suspension action by the Nasdaq staff pending the issuance of the Hearing' s Panel decision. The Hearing took place on November 9, 2023. Prior to the date of the Hearing, we effectuated a reverse stock split of our issued and outstanding shares of common stock at a ratio of 1- for- 25. The reverse stock split became effective on October 25, 2023, and our common stock began trading on a post- reverse stock split basis on the Nasdaq on October 27, 2023. To satisfy the minimum bid requirement, our common stock was required to trade at above $ 1. 00 per share for at least 10 trading days, and this was achieved on November 9, 2023. We therefore believe that the Hearing Panel should find that we have regained compliance with the Minimum Bid Requirement. At the Hearing on November 9, 2023, we presented our plan to regain compliance with the minimum stockholders' equity requirement (the " Equity Rule "), which plan includes raising additional equity capital. On November 30, 2023, we received a letter from the Hearings Panel that, subject to certain conditions, the Hearings Panel granted our request to continue to be listed on Nasdaq. These conditions include providing an update as to our plan to regain compliance with the Equity Rule as well as demonstrating compliance by March 19, 2024. On February 23, 2024 we presented our plan of compliance to the Hearings Committee. We believe that we will be able to regain and maintain compliance with both the minimum bid requirement and the minimum stockholders' equity requirement, which would allow our common stock to continue to trade on Nasdaq. However, there can be no assurance that the Hearing Panel will agree with our plan, that will be provided adequate time to achieve compliance or, even** if **provided adequate time, that** we ~~are~~ **will in fact be** ~~unable~~ -- **able** to ~~comply~~ **regain and maintain compliance** with **both requirements, in which case our common stock would be subject to delisting from Nasdaq. Such a delisting could have a material adverse effect on our stock price, the ability of our stockholders to buy or sell their common stock, and our reputation,** all ~~continued listing requirements~~ **of which could make it significantly more difficult to operate our company** . **- 51-** The terms of our ~~January~~ **November** 2023 private placement **and February 2024 warrant exercise transaction** could hamper our fundraising efforts. In ~~January~~ **November** 2023, we ~~engaged~~ **consummated** in ~~an a~~ $ ~~8~~ **4** million private placement with a single institutional investor. The terms of the Securities Purchase Agreement related to such private placement ~~contains~~ **contain** certain restrictions that could hamper our future fundraising efforts. Specifically: (a) from ~~January 5~~ **November 2** , 2023 until ~~May 9, 2023~~ **forty- five (45) days after the effective date of the registration statement** , neither our company nor any subsidiary of our company shall (i) issue, enter into any agreement to issue or announce the issuance or proposed issuance of any shares of common stock or securities convertible into or exercisable for common stock or (ii) file any registration statement or any amendment or supplement thereto, in each case other than as contemplated by the Registration Rights Agreement we entered into with the investor; or (b) from ~~January 5~~ **November 2** , 2023 until ~~November 8, 2023~~ **twelve (12) months after the effective date of the registration statement** , we shall be prohibited from effecting or entering into an agreement to effect any issuance by us or any of our subsidiaries of any shares of common stock or securities convertible into or exercisable for common stock (or a combination of units thereof) involving a " variable rate transaction ", meaning a transaction in which we (i) issue or sell any debt or equity securities that are convertible into, exchangeable or exercisable for, or include the right to receive, additional shares of common stock either (i) at a conversion price, exercise price or exchange rate or other price that is based upon, and / or varies with, the trading prices of or quotations for the shares of common stock at any time after the initial issuance of such debt or equity securities or (ii) with a conversion, exercise or exchange price that is subject to being reset at some future date after the initial issuance of such debt or equity security or upon the occurrence of specified or contingent events directly or indirectly related to our business or the market for the common stock or (ii) enter into, or effect a transaction under, any agreement, including, but not limited to, an equity line of credit, whereby we may issue securities at a future determined price. **On February 14 2024, we entered into a warrant inducement letter (the " Inducement Agreement ") with the same institutional investor. The terms of this Inducement Agreement contain certain restrictions that could hamper our future fundraising efforts. Specifically: (a)**

from February 14, 2024 until forty- five (45) days after the closing date of the Inducement Agreement, neither our Company nor any subsidiary of our Company shall (i) issue, enter into any agreement to issue or announce the issuance or proposed issuance of any shares of common stock or securities convertible into or exercisable for common stock or (ii) file any registration statement or any amendment or supplement thereto, in each case other than as contemplated by the Registration Rights Agreement we entered into with the investor (b) From February 14, 2024 until six (6) months after the effective date of the registration statement we are required to file in connection with the transactions contemplated by the Inducement Agreement, we shall be prohibited from effecting or entering into an agreement to effect any issuance by us or any of our subsidiaries of any shares of common stock or securities convertible into or exercisable for common stock (or a combination of units thereof) involving a " variable rate transaction ", meaning a transaction in which we (i) issue or sell any debt or equity securities that are convertible into, exchangeable or exercisable for, or include the right to receive, additional shares of common stock either (i) at a conversion price, exercise price or exchange rate or other price that is based upon, and / or varies with, the trading prices of or quotations for the shares of common stock at any time after the initial issuance of such debt or equity securities or (ii) with a conversion, exercise or exchange price that is subject to being reset at some future date after the initial issuance of such debt or equity security or upon the occurrence of specified or contingent events directly or indirectly related to our business or the market for the common stock or (ii) enter into, or effect a transaction under, any agreement, including, but not limited to, an equity line of credit, whereby we may issue securities at a future determined price. The existence of these restrictions could reduce the number of fundraising structures available to us, or could discourage potential investors from making offers of investment to us. As a result, we may find it more difficult to raise required funding at times and on terms we deem desirable, and our inability to raise necessary funding could have a material adverse effect on our company and stock price **. This is of particular risk to our company as of the date of this Report, since we need to raise additional equity capital to bolster our stockholders' equity for Nasdaq Stock Market purposes and to fund and grow our business generally** . If our shares of common stock become subject to the penny stock rules, it would become more difficult to trade our shares. The Securities and Exchange Commission (or SEC) has adopted rules that regulate broker- dealer practices in connection with transactions in penny stocks. Penny stocks are generally equity securities with a price of less than $ 5. 00, other than securities registered on certain national securities exchanges or authorized for quotation on certain automated quotation systems, provided that current price and volume information with respect to transactions in such securities is provided by the exchange or system. If we do not obtain or retain a listing on Nasdaq and if the price of our common stock is less than $ 5. 00, our common stock will be deemed a penny stock. The penny stock rules require a broker- dealer, before a transaction in a penny stock not otherwise exempt from those rules, to deliver a standardized risk disclosure document containing specified information. In addition, the penny stock rules require that before effecting any transaction in a penny stock not otherwise exempt from those rules, a broker- dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive (i) the purchaser' s written acknowledgment of the receipt of a risk disclosure statement; (ii) a written agreement to transactions involving penny stocks; and (iii) a signed and dated copy of a written suitability statement. These disclosure requirements may have the effect of reducing the trading activity in the secondary market for our common stock, and therefore stockholders may have difficulty selling their shares.- 52- There can be no assurance that we will ever provide liquidity to our investors through a sale of our company. While acquisitions of medical technology companies like ours are not uncommon, potential investors are cautioned that no assurances can be given that any form of merger, combination, or sale of our company will take place relating to our company, or that any merger, combination, or sale, even if consummated, would provide liquidity or a profit for our investors. You should not invest in our company with the expectation that we will be able to sell the business in order to provide liquidity or a profit for our investors ~~. Our officers and directors may have the ability to exert significant influence over our affairs, including the outcome of matters requiring stockholder approval. Our officers and directors and their affiliates (primarily Kirk Huntsman) currently own shares of common stock, in the aggregate, representing approximately 7. 6 % of our outstanding voting capital stock. In addition, Dr. Dave Singh, our former Chief Medical Officer and director, owns an additional 10. 8 % of our outstanding voting stock. As a result, if these stockholders and any associated stockholders were to choose to act together, they have and may continue to be able to exert control over certain matters submitted to our stockholders for approval by having the ability to block certain proposals. For example, these persons, if they choose to act collectively, would have the ability to vote against and block a proposed merger, consolidation or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent an acquisition of our company on terms that other stockholders may desire~~ . Actions of activist shareholders could be disruptive and potentially costly and the possibility that activist shareholders may seek changes that conflict with our strategic direction could cause uncertainty about the strategic direction of our business. Activist investors or other stockholders who disagree with our management may attempt to effect changes in our strategic direction and how our company is governed or may seek to acquire control over our company. Some investors (commonly known as " activist investors ") seek to increase short- term stockholder value by advocating corporate actions such as financial restructuring, increased borrowing, special dividends, stock repurchases, or even sales of assets or the entire company. Activist campaigns can also seek to change the composition of our ~~Board~~ **board** of ~~Directors~~ **directors** , and campaigns that contest or conflict with our strategic direction could have an adverse effect on our results of operations and financial condition as responding to proxy contests and other actions by activist shareholders can disrupt our operations, be costly and time- consuming, and divert the attention of our ~~Board~~ **board** of ~~Directors~~ **directors** and senior management from the pursuit of our business strategies. In addition, perceived uncertainties as to our future direction that can arise from potential changes to the composition of our ~~Board~~ **board** of ~~Directors~~ **directors** sought by activists may lead to the perception of a change in the direction of the business, instability or lack of continuity which may be exploited by our competitors, may cause concern to our current or potential customers or other partners, may result in the loss of potential business opportunities and may make it more difficult to attract

and retain qualified personnel and business partners. These types of actions could divert our management' s attention from our business or cause significant fluctuations in our stock price based on temporary or speculative market perceptions or other factors that do not necessarily reflect the underlying fundamentals and prospects of our business, all of which could have a material adverse effect on our company. We are an " emerging growth company, " and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors. We are an " emerging growth company, " or EGC, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. We will remain an EGC until the earlier of: (i) the last day of the fiscal year in which we have total annual gross revenue of $ 1. ~~07~~ **235** billion or more; (ii) the last day of the fiscal year following the fifth anniversary of the date of the completion of our initial public offering; (iii) the date on which we have issued more than $ 1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC. For so long as we remain an EGC, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include: ● not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act, or Section 404;- 53- ● not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor' s report providing additional information about the audit and the financial statements; ● being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced " Management' s Discussion and Analysis of Financial Condition and Results of Operations " disclosure; ● reduced disclosure obligations regarding executive compensation; and ● exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We may choose to take advantage of some, but not all, of the available exemptions. We have taken advantage of reduced reporting burdens in this Annual Report on Form 10- K. In particular, we have not included all of the executive compensation information that would be required if we were not an EGC. We cannot predict whether investors will find our common stock less attractive if we rely on certain or all of these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We continue to incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives. As a public company, and particularly after we are no longer an EGC, we will incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes- Oxley Act and rules subsequently implemented by the SEC and Nasdaq have imposed various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time- consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance. Pursuant to Section 404, we will be required to furnish a report by our management on our internal control over financial reporting, including an attestation report on internal control over financial reporting issued by our independent registered public accounting firm if certain criteria are met. However, while we remain an EGC, 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 will be 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 neither we nor our independent registered public accounting firm will be able to conclude within the prescribed timeframe that our internal control over financial reporting is effective as required by Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.- 54- Certain provisions of our Certificate of Incorporation may make it more difficult for a third party to effect a change- of- control. Our Certificate of Incorporation authorizes our ~~Board~~ **board** of ~~Directors~~ **directors** to issue up to 50, 000, 000 shares of preferred stock. The preferred stock may be issued in one or more series, the terms of which may be determined at the time of issuance by our ~~Board~~ **board** of ~~Directors~~ **directors** without further action by the stockholders. These terms may include preferences as to dividends and liquidation, conversion rights, redemption rights and sinking fund provisions. The issuance of any preferred stock could diminish the rights of holders of our common stock, and therefore could reduce the value of such common stock. In addition, specific rights granted to future holders of preferred stock could be used to restrict our ability to merge with, or sell assets to, a third party. The ability of our ~~Board~~ **board** of ~~Directors~~ **directors** to issue preferred stock could make it more difficult, delay, discourage, prevent or make it more costly to acquire or effect a change- in- control, which in turn could prevent our stockholders from recognizing a gain in the event that a favorable offer is extended and could materially and negatively affect the market price of our common stock. Our bylaws designate certain courts as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees. Our bylaws provide that, unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, the federal district court for the District of Delaware) will be the exclusive forum for: (i) any derivative action or proceeding brought on behalf of our company; (ii) any action asserting a claim for breach of a fiduciary duty owed by any director, officer, employee, or agent of ours to us or our stockholders; (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, the Certificate of Incorporation, or the bylaws; and (iv) any action

asserting a claim governed by the internal affairs doctrine (the " Delaware Forum Provision "). Our bylaws further provide that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America shall be the sole and exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act (the " Federal Forum Provision "). In addition, our bylaws provide that any person or entity purchasing or otherwise acquiring any interest in shares of our common stock is deemed to have notice of and consented to the Delaware Forum Provision and the Federal Forum Provision. Section 27 of the Securities Exchange Act of 1934, as amended (the " Exchange Act "), creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. As a result, the Delaware Forum Provision will not apply to suits brought to enforce any duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. We note, however, that there is uncertainty as to whether a court would enforce this provision and that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. We recognize that the Delaware Forum Provision and the Federal Forum Provision in our bylaws may impose additional litigation costs on stockholders in pursuing any such claims, particularly if the stockholders do not reside in or near the State of Delaware. Additionally, the Delaware Forum Provision and the Federal Forum Provision may limit our stockholders' ability to bring a claim in a forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage such 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 were " facially valid " under Delaware law, there is uncertainty as to whether other courts will enforce the Federal Forum Provision. If the Federal Forum Provision is found to be unenforceable, we may incur additional costs associated with resolving such matters. The Federal Forum Provision may also impose additional litigation costs on stockholders who assert that the provision is not enforceable or invalid. The Court of Chancery of the State of Delaware and the United States District Court 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.- 55- Limitations on director and officer liability and indemnification of our officers and directors by us may discourage stockholders from bringing suit against an officer or director. Our Certificate of Incorporation and bylaws provide that, to the fullest extent permitted by Delaware law, as it presently exists or may be amended from time to time, a director shall not be personally liable to us or our stockholders for monetary damages for any breach of fiduciary duty as a director. Under Delaware law, this limitation of liability does not extend to, among other things, acts or omissions which involve intentional misconduct, fraud or knowing violation of law, or unlawful payments of dividends. These provisions may discourage stockholders from bringing suit against a director or officer for breach of fiduciary duty and may reduce the likelihood of derivative litigation brought by stockholders on our behalf against a director or officer. We are responsible for the indemnification of our officers and directors. Should our officers and / or directors require us to contribute to their defense, we may be required to spend significant amounts of our capital. Our Certificate of Incorporation and bylaws also provide for the indemnification of our directors, officers, employees, and agents, under certain circumstances, against attorney' s fees and other expenses incurred by them in any litigation to which they become a party arising from their association with or activities on behalf of our company. This indemnification policy could result in substantial expenditures, which we may be unable to recoup. If these expenditures are significant or involve issues which result in significant liability for our key personnel, we may be unable to continue operating as a going concern. Our ability to use our net operating losses and research and development credit carryforwards to offset future taxable income may limited, perhaps substantially. In general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (or the Code), a corporation that undergoes an " ownership change, " generally defined as a greater than 50 % change by value in its equity ownership over a three- year period, is subject to limitations on its ability to utilize its pre- change net operating losses (" NOLs "), carryforwards to offset future taxable income. Our existing NOLs may be subject to limitations arising from previous ownership changes. If we undergo, or are deemed to have previously undergone, an ownership change, our ability to utilize NOLs carryforwards could be limited (perhaps substantially) by Sections 382 and 383 of the Code. Additionally, future changes in our stock ownership, some of which might be beyond our control, could result in an ownership change under Section 382 of the Code. For these reasons, in the event we experience or are deemed to have experienced an " ownership change " for these purposes, we may not be able to utilize a material or even a substantial portion of the NOLs carryforwards, even if we attain profitability. We have not completed a Code Section 382 analysis regarding any limitation on our NOL carryforwards. The financial and operational projections that we may make from time to time are subject to inherent risks. The projections that our management may provide from time to time (including, but not limited to, those relating to market sizes and other financial or operational matters) reflect numerous assumptions made by management, including assumptions with respect to our specific as well as general business, economic, market and financial conditions and other matters, all of which are difficult to predict and many of which are beyond our control. Accordingly, there is a risk that the assumptions made in preparing the projections, or the projections themselves, will prove inaccurate. There will be differences between actual and projected results, and actual results may be materially different from those contained in the projections. The inclusion of the projections in this Annual Report should not be regarded as an indication that we or our management or representatives considered or consider the projections to be a reliable prediction of future events, and the projections should not be relied upon as such. If we were to dissolve, the holders of our securities may lose all or substantial amounts of their investments. If we were to dissolve as a corporation, as part of ceasing to do business or otherwise, we may be required to pay all amounts owed to any creditors before distributing any assets to the investors. There is a risk that in the event of such a dissolution, there will be insufficient funds to repay amounts owed to holders of any of our indebtedness and insufficient assets to distribute to our other investors, in which case investors could lose their entire investment. ~~- 56-~~ An investment in our company may involve tax implications, and you are encouraged to consult your own advisors as neither we

nor any related party is offering any tax assurances or guidance regarding our company or your investment. The formation of our company and our financings, as well as an investment in our company generally, involves complex federal, state and local income tax considerations. Neither the Internal Revenue Service nor any state or local taxing authority has reviewed the transactions described herein, and may take different positions than the ones contemplated by management. You are strongly urged to consult your own tax and other advisors prior to investing, as neither we nor any of our officers, directors or related parties is offering you tax or similar advice, nor are any such persons making any representations and warranties regarding such matters. **- 56-** Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain. We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. This means that it is very unlikely that we will pay dividends on our shares of common stock. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future. If securities or industry analysts do not publish or cease publishing research or reports about us, our business or our market, or if they change their recommendations regarding our common stock adversely, the price of our common stock and trading volume could decline. The trading market for our common stock may be influenced by the research and reports that securities or industry analysts may publish about us, our business, our market or our competitors. If any of the analysts who may cover us change their recommendation regarding our common stock adversely, or provide more favorable relative recommendations about our competitors, the price of our common stock would likely decline. If any analyst who may cover us was to cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause the price of our common stock or trading volume to decline. Item 1B. Unresolved Staff Comments.