Vivos

Vivos Therapeutics, Inc. (Nasdaq:VVOS)

2021 ANNUAL REPORT

to Stockholders

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the Fiscal Year Ended December 31, 2021

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the Transition Period from to

Commission File Number: **001-39796**

Vivos Therapeutics, Inc.
(Exact Name of Registrant as Specified in its Charter)

Delaware	**81-3224056**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
9137 Ridgeline Boulevard, Suite 135, Highlands Ranch, CO	**80129**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(844) 672-4357**

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol(s)	Name of exchange on which registered
Common stock, par value $0.0001 per share	**VVOS**	**Nasdaq Capital Market**

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ☐ NO ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. YES ☐ NO ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES ☒ NO ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). YES ☒ NO ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer", "accelerated filer", "smaller reporting company", or "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☒	Smaller reporting company ☒
	Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES ☐ NO ☒

As of June 30, 2021, the last business day of the second fiscal quarter, the aggregate market value of the registrant's voting stock held by non-affiliates, was approximately $88.3 million based on the last reported sales price of $4.95 as quoted on the Nasdaq Capital Market on such date.

The registrant had 23,012,119 shares of its $0.0001 par value Common Stock outstanding as of March 31, 2022.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements that reflect our current expectations and views of future events. The forward-looking statements are contained principally in the sections entitled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations." Readers are cautioned that known and unknown risks, uncertainties and other factors, including those over which we may have no control and others listed in the "Risk Factors" section of this Annual Report on Form 10-K, may cause our actual results, performance or achievements to be materially different from those expressed or implied by the forward-looking statements.

You can identify some of these forward-looking statements by words or phrases such as "may," "will," "expect," "anticipate," "aim," "estimate," "intend," "plan," "believe," "is/are likely to," "potential," "continue" or other similar expressions. We have based these forward-looking statements largely on our current expectations and projections about future events that we believe may affect our financial condition, results of operations, business strategy and financial needs.

These forward-looking statements include statements relating to:

- our ability to continue to refine and execute our business plan, including the recruitment of dentists to enroll in our Vivos Integrated Practice (VIP) program and utilize The Vivos Method;
- the understanding and adoption by dentists and other healthcare professionals of The Vivos Method as a treatment for dentofacial abnormalities and/or mild to moderate obstructive sleep apnea (OSA) and snoring in adults;
- our expectations concerning the effectiveness of treatment using The Vivos Method and patient relapse after completion of treatment;
- the potential financial benefits to VIP dentists from treating patients with The Vivos Method;
- our potential profit margin from the enrollment of VIPs, VIP service fees, sales of The Vivos Method protocols and appliances and leases of SleepImage home sleep testing rings as part of the VivoScore Program;
- our ability to properly train VIPs in the use of The Vivos Method and other services we offer independent dentist for use in treating their patients in their dental practices;
- our ability to formulate, implement and modify as necessary effective sales, marketing and strategic initiatives to drive revenue growth (including, for example, our Medical Integration Division and SleepImage® home sleep apnea test);
- the viability of our current intellectual property and intellectual property created in the future;
- acceptance by the marketplace of the products and services that we market;
- government regulations and our ability to obtain applicable regulatory approvals and comply with government regulations including under healthcare laws and the rules and regulations of the U.S. Food and Drug Administration;
- our ability to retain key employees;
- adverse changes in general market conditions for medical devices and the products and services we offer;
- our ability to generate cash flow and profitability and continue as a going concern;
- our future financing plans; and
- our ability to adapt to changes in market conditions (including as a result of the COVID-19 pandemic) which could impair our operations and financial performance.

These forward-looking statements involve numerous risks and uncertainties. Although we believe that our expectations expressed in these forward-looking statements are reasonable, our expectations may later be found to be incorrect. Our actual results of operations or the results of other matters that we anticipate herein could be materially different from our expectations. Important risks and factors that could cause our actual results to be materially different from our expectations are generally set forth in "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations," "Business," "Regulation" and other sections in this Annual Report on Form 10-K. You should thoroughly read this Annual Report on Form 10-K and the documents that we refer to with the understanding that our actual future results may be materially different from and worse than what we expect. We qualify all of our forward-looking statements by these cautionary statements.

The forward-looking statements made in this Annual Report on Form 10-K relate only to events or information as of the date on which the statements are made in this Annual Report on Form 10-K. Except as required by law, we undertake no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise, after the date on which the statements are made or to reflect the occurrence of unanticipated events. You should read this Annual Report on Form 10-K and the documents that we refer to in this Annual Report on Form 10-K and have filed as exhibits to this Annual Report on Form 10-K, completely and with the understanding that our actual future results may be materially different from what we expect.

SUMMARY OF MATERIAL RISKS ASSOCIATED WITH OUR BUSINESS

The following is a summary of certain risks, uncertainties and other factors related to our company. These do not represent all of the risks we face. You should carefully consider all of the risk factors presented in "Item 1A. Risk Factors" (some of which are not summarized below) and all other information contained in this Report, including the financial statements which are a part of this Report, in order to a more complete picture of the risk factors we face.

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.
- We have a history of operating losses and may never achieve cash flow positive or profitable results of operations.
- Our VIP program is a relatively new business model for us, and management has limited experience operating this model.
- We will need to raise additional capital 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, which could adversely affect our liquidity, financial position, and ability to continue operations.
- We have identified a material weakness in our internal control over financial reporting.
- We expect to derive a substantial portion of our prospective future revenue from sales of our appliances and protocols, which leaves us reliant on the commercial viability of The Vivos Method.
- We will not be successful if The Vivos Method is not sufficiently adopted by the medical and dental communities, including independent practitioners and dental service organizations.
- We may not be able to successfully implement our growth strategies for our VIPs, which could harm 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 dental practices.
- 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.
- 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.
- Further clinical studies of The Vivos Method may adversely impact our ability to generate revenue if they do not demonstrate that The Vivos Method is effective for new indications.
- 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.
- Our products and third-party contract manufacturing activities are subject to extensive governmental regulation that could prevent us from selling Vivos appliances or introducing new and/or improved products in the United States or internationally.
- We face significant competition in the market for treating sleep breathing disorders, and we may be unable to manage competitive pressures.

- We may not be able to protect our patents and proprietary technology and may become subject to intellectual property claims or litigation.

- We face the risk of product liability claims that could be expensive, divert management's attention and harm our reputation and business. We may not be able to maintain adequate product liability insurance.

- If we are unable to comply, or have not fully complied, with federal and state healthcare fraud and abuse laws, false claims laws, health information privacy and security laws, and other healthcare laws and regulations, we could face substantial penalties.

- The misuse or off-label use of our appliances and associated protocols could 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.

Risks Related to Our Products and Regulation

- Our failure to obtain government approvals, or to comply with ongoing 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.

- We cannot assure that we will be able to complete any required clinical trial programs successfully within any specific time, and if such clinical trials take longer to complete than we project, our ability to execute our current business strategy will be adversely affected.

- Modifications to our appliances 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.

- 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.

- 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.

- Our Medical Integration Division business line may implicate federal and state laws involving the practice of medicine and related anti-kickback and similar laws.

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.

- The market price of our common stock may be highly volatile resulting in substantial losses for investors.

- Our failure to meet the continuing listing requirements of The Nasdaq Capital Market could result in a de-listing of our securities.

- Our officers and directors may have the ability to exert significant influence over our affairs, including the outcome of matters requiring stockholder approval.

PART I

Item 1. Business

Overview

We are a revenue stage medical technology company focused on the development and commercialization of a suite of innovative diagnostic and treatment modalities for patients with dentofacial abnormalities and/or patients with mild to moderate obstructive sleep apnea (OSA) and snoring in adults. We believe our proprietary oral appliances and associated protocols represent a significant improvement in the treatment of mild to moderate OSA versus other treatments such as continuous positive airway pressure (or CPAP) or palliative oral appliance therapies. We call our OSA treatment protocol ***The Vivos Method***.

The Vivos Method is an advanced therapeutic protocol, which often combines the use of customized oral appliance specifications and proprietary clinical protocols developed by our company and prescribed by specially trained dentists in cooperation with their medical colleagues. The Vivos Method features our proprietary clinical protocols combined with the following oral appliances:

- ***Mandibular Repositioning Nighttime Appliance*** (or mRNA appliance®) has 510(k) clearance from the FDA as a Class II medical device for the treatment of snoring and mild to moderate OSA in adults.

- ***Modified Mandibular Repositioning Nighttime Appliance*** (or mmRNA appliance), for which we were granted FDA Class II market clearance in August 2021 for treating mild to moderate OSA, jaw reposition and snoring in adults.

- ***Daytime Nighttime Appliance*** (or DNA appliance®) is an FDA-registered product and is currently used by Vivos-trained clinicians accordingly. We instruct all dentists prescribing the DNA appliance about the device's approved indications of use and of the fact that the DNA appliance is a Class I FDA registered oral appliance for expansion.

- ***Vivos Guides*** are pre-formed, flexible, BPA-free, base polymer intraoral guide and rescue appliances. The Guides are an FDA-registered product for orthodontic tooth positioning.

We believe The Vivos Method appliance technology and associated protocols represents the first non-surgical, non-invasive and cost-effective treatment for people with dentofacial abnormalities and/or patients diagnosed with mild to moderate obstructive sleep apnea (OSA) and snoring in adults. Combining technologies and protocols that alter the size, shape and position of the tissues of a patient's upper airway, The Vivos Method opens oral and airway space and may significantly reduce symptoms and conditions associated with mild to moderate OSA.

Published studies have shown that using our customized appliances and clinical protocols led to significantly lower Apnea Hypopnea Index scores and improved other conditions associated with OSA, and The Vivos Method is estimated to be effective (within the scope of the U.S. Food and Drug Administration (or FDA) cleared uses) in approximately 80% of cases of OSA where patients are compliant with clinical protocols. Our patented oral appliances have been utilized in approximately 25,000 patients treated worldwide by more than 1,450 trained dentists.

The House of Delegates of the American Dental Association in 2017 adopted a policy statement describing the important role dentists can play in helping identify patients at greater risk of sleep related breathing disorders. By focusing our business model around dentists, we fulfil this role by training dentists and providing the support to use The Vivos Method with their patients that suffer from dentofacial abnormalities and/or mild to moderate OSA and snoring. Our program to train dentists and offer them other value-added services is called the ***Vivos Integrated Practice (VIP)*** program. The VIP program provides dentists with a strong economic incentive to provide this treatment and prescribe The Vivos Method, together with practice support services.

Sleep apnea is a serious and chronic disease that negatively impacts a patient's sleep, health, and quality of life. According to a 2019 article published in *Chest Physician*, it is estimated that OSA afflicts 54 million adults in the U.S. alone, and according to a 2016 report by Frost & Sullivan, OSA has an annual societal cost of over $149.6 billion. According to the study "*Global Prevalence of Obstructive Sleep Apnea (OSA)*" conducted by an international panel of leading researchers, nearly 1 billion people worldwide have sleep apnea, and as many as 80% remain undiagnosed. Research has shown that when left untreated, OSA can increase the risk of comorbidities, such as high blood pressure, heart failure, stroke, diabetes, dementia, chronic pain and other debilitating, life-threatening diseases.

In February 2021, we launched our screening and home sleep test ("HST") program (which we call our ***VivoScore Program***) featuring ***SleepImage®*** technology, a 510(k) cleared ring-based recorder and diagnostic platform for home sleep apnea testing. We market and distribute our SleepImage HST in the U.S. and Canada pursuant to a licensing agreement with MyCardio LLC. We believe our SleepImage HST offers significant commercial advantages over existing home sleep apnea products and technologies in the market and may enable healthcare providers to more efficiently screen, diagnose and initiate treatment for OSA in their patients, which could result in more patients being treated through The Vivos Method. Initially, we anticipated increased revenue from our HST based on an expected increase in total patients tested for OSA and a corresponding increase in patient enrolment in Vivos Method treatment. Throughout 2021, we successfully conducted 15 training sessions conducted by our personnel on the VivoScore Program and screening and home sleep testing using the SleepImage® HST, which were attended by approximately 800 dentists and their staff.

In January 2022, we announced significant increases across several key metrics for our SleepImage HST, including in particular, for the three-months ended December 31, 2021, versus the three-months ended December 31, 2020: (i) an 18 times increase in the total number of HSTs given across our VIP network, (ii) a 5.7 times increase in the number of VIPs administering HSTs via the VivoScore Program and (iii) a 3 times increase in the average number of HSTs being administered per VIP. We believe this performance gain in home sleep testing allowed us to renegotiate our commercial agreement with MyCardio LLC to lower costs and convert the entire diagnostic program from a loss leader aimed primarily at stimulating new case starts with sleep apnea treatment using The Vivos Method to a potential recurring revenue center. Under the revised agreement, we will lease out the SleepImage ring recorders to VIPs at a fixed price that includes a full month's worth of diagnostic sleep test reports. This potential new revenue center is as yet unproven, but we believe we will see positive results during 2022.

Our Mission

Our mission is to rid the world of OSA. We believe we are well-positioned with what we consider to be a disruptive technology in The Vivos Method aimed at treating dentofacial abnormalities and/or mild to moderate OSA and snoring, with a clear first-mover strategy in penetrating the dental market as a means of treating dental conditions and OSA, compelling economics at each level of the delivery chain, and a talented team of experienced professionals who are passionate about what we do and driven to deliver results.

Our Market Opportunity

According to an August 2019 article published in the Lancet, an estimated 936 million adults globally aged 30-69 years (men and women) have mild to severe obstructive sleep apnea, which includes 425 million adults aged 30-69 years who have moderate to severe obstructive sleep apnea. The number of affected individuals with OSA was highest in China, followed by the U.S., Brazil, and India. The article indicated that 1 billion people (inclusive of children) are affected with OSA, with prevalence exceeding 50% in some countries. We therefore believe that effective diagnostic and treatment strategies are needed to minimize the negative health impacts of OSA and to maximize cost-effectiveness.

Estimates from publicly available information vary as to the extent of obstructive sleep apnea in the United States, but we believe the market is significant. According to a 2010 publicly available analysis from researchers at the Harvard Medical School Division of Sleep Medicine, mild obstructive sleep apnea is defined by an apnea-hypopnea index (or AHI) of between 5 and 15 and has a prevalence of 8-11% of the adult population in the United States. A 2004 study published in the Journal of the American Medical Association stated the prevalence of mild obstructive sleep apnea is one in five adults. Based on our analysis of the available public information, we estimate that approximately 15% of the adult population in the United States and Canada suffers from OSA. Based on the estimated total adult population of 284 million in the United States and Canada, we believe the total addressable United States and Canadian market is approximately 43 million adults. Our estimates set forth below relating to the intended uses of The Vivos Method are also based in part upon data found in the study *Oral Appliance Treatment for Obstructive Sleep Apnea: An Update,* published publicly by the National Institutes of Health in 2014. Targeted treatment projections identified by this method of sleep titration were found to result in effective treatment in 87% of patients predicted to be successfully treated of OSA in an initial study. To be conservative and based on available data and our internal market analysis, we estimate that over 80% of individuals diagnosed with OSA in the North American addressable market may be candidates for The Vivos Method, leaving us with a total addressable consumer market of over 43.2 million adults.

We currently charge clinicians an average sales price of approximately $1,600 per adult case for The Vivos Method. There are approximately 200,000 general dentists and dental specialists in the United States and another 30,000 in Canada who could potentially offer the Vivos Method to their patients. Based on the addressable U.S. and Canadian consumer market described above and average sales price, we believe the addressable consumer market for adults in the United States and Canada is approximately $69 billion.

According to a March 2021 Sleep Apnea Devices Market Size & Share Report, *"Sleep Apnea Devices Market Size, Share & Trends Analysis Report By Product Type (Diagnostic Devices, Therapeutic Devices, Sleep Apnea Masks), By Region (North America, Europe, APAC, Latin America, MEA), And Segment Forecasts, 2021 – 2028"*, the global sleep apnea devices market size was valued at $3.7 billion in 2020 and is expected to expand at a compound annual growth rate (CAGR) of 6.2% from 2021 to 2028. According to an American Sleep Association study published in 2020, an estimated 50 million to 70 million people in the U.S. are suffering from some form of sleep disorders. Moreover, according to Canadian Respiratory Journal in 2014, around 5.4 million adults in Canada were diagnosed with sleep apnea or were at higher risk of developing OSA. According to a study conducted by ResMed in 2018, around 175 million people in Europe were suffering from sleep apnea."

Our Treatment Alternative for OSA – The Vivos Method

The Vivos Method is a non-invasive, non-surgical, non-pharmaceutical, multi-disciplinary treatment modality for the treatment of dentofacial abnormalities and/or mild to moderate OSA and snoring. Proprietary and virtually painless, The Vivos Method may enhance and increase the upper airway and offers patients what we believe to be an effective treatment alternative based on clinical retrospective data showing that some patients diagnosed with mild to moderate OSA and snoring symptoms. are improving. Based on feedback from independent VIP and their patient we have received, we believe initial therapeutic benefits from using the protocols and devices are often achieved relatively quickly (in days or weeks) and final clinical results are typically achieved in 12 to 24 months), all at a relatively low cost to consumers ranging between $7,000 and $10,000 for adults and $3,500 to $6,000 for children (costs vary by provider) when compared to other options such as surgery.

We believe that The Vivos Method alters the size, shape and position of the tissues that surround and comprise the functional space known as the upper airway. This belief is based on retrospective raw data with validated before and after sleep studies and Cone Beam Computerized Tomography (CBCT) scans from treating clinicians and patient testimony. As The Vivos Method treatment process progresses, the airway expands, with many patients reporting a significant reduction of their mild to moderate OSA and snoring symptoms. Our primary products used in The Vivos Method is our mRNA appliance®, and our mmRNA appliance® which are specifically designed, custom oral appliance that are worn primarily in the evening hours and overnight and are available for adults. The treatment time may range from 12 to 24 months. Our appliances may require periodic adjustments some of which can be performed by the patient and others that are typically rendered at the dental office where treatment was initiated. Through the course of treatment with The Vivos Method, patients have reported a variety of outcomes, including:

- Reduction of snoring;
- Reduction in AHI level and/or other indicators of mild to moderate OSA;
- Relief of mild to moderate OSA symptoms;
- Restoration and improvement of normal (nasal) breathing;
- Improvement in overall sleep quality;
- Reduction in the need for other lifetime treatment options such as CPAP;
- Restoration and maintenance of proper facial symmetry and alignment;
- Dentofacial and orthodontic improvement and/or correction;
- Resolution of TMJ pain, clicking, and locking; and
- Facial aesthetic improvement, including a broader smile and reduced 'gummy smile'.

Our Growth Strategy

Our goal is to be the global leader in providing a clinically effective non-surgical, non-invasive, non-pharmaceutical, and low-cost alternative for patients with dentofacial abnormalities and/or mild to moderate OSA and snoring in adults. We believe the following strategies will play a critical role in achieve this goal and our future growth:

- ***Expand our North American (U.S. and Canada) sales and marketing organization to drive adoption of The Vivos Method.*** We intend to continue the growth our sales and marketing organization and related strategic programs in order to target and expand our network of Vivos Integrated Practices.

- ***Drive medical and dental community awareness of The Vivos Method.*** We intend to continue to promote awareness of the value proposition of The Vivos Method through training and educating dentists, physicians, and other healthcare providers, including at our Vivos Institute in Denver, Colorado.

- ***Continue to establish indirect marketing channels***. We have entered, and plan to expand, strategic alliances within the medical and dental communities to increase awareness of our products. For example, in August 2021, we announced a new cooperative relationship with Empower Sleep, a San Bernardino, California-based company empowering patients with affordable, accessible and personalized telemedicine sleep care, to provide critical diagnostic and medical consultation services to people across North America who suffer from OSA. We plan to leverage Empower Sleep's core technologies to provide a user-friendly platform with personalized insights for our products for patients who are being screened for OSA by North American dentists and other healthcare providers.

- ***Build consumer awareness of The Vivos Method.*** We also plan to continue building consumer awareness through our direct-to-patient marketing initiatives which we anticipate will include celebrity endorsements, paid search, radio, television, social media, influencers, company sponsored events, corporate wellness programs, and online video.

- ***Invest in research and development to drive innovation and expand indications.*** We are committed to ongoing research and development, and we intend to invest in our business to further improve our products and validate our value proposition.

- ***Pursue strategically adjacent markets and international opportunities.*** We believe there is a significant opportunity for our products outside the United States. We have begun an initial assessment of the development and commercialization of The Vivos Method for markets outside of North America, and we plan to conduct further strategic evaluation of such markets as we expand our market penetration throughout the United States and Canada.

Our Revenue Model

Our revenue is currently derived from the following primary sources:

- ***VIP office training and enrollment fees***. These fees are comprised of one-time, up-front fees, as well as optional renewal fees after 12 months.

- ***Recurring Vivos appliance sales***. Once we train the VIP on how dentists can help treat OSA, the goal is to have them initiate "new case starts" with patients, which leads to sales of our appliances and guides.

- ***Recurring VIP subscription fees.*** These are recurring fees that a portion of our VIPs pay us to receive additional value-added services and training.

- ***SleepImage HST revenue***. As described above, we recently modified our agreement with MyCardio LLC relating to our SleepImage HST for sleep apnea, which creates the potential for revenue from our leasing of SleepImage HST ring recorders to our VIPs as part of the VivoScore Program.

- ***The Vivos Institute.*** Opened in August 2021, our 15,000 square foot Vivos Institute provides advanced post-graduate education and certification to dentists, dental teams, and other healthcare professionals in a live and hands-on setting in the emerging science of what we call Vivos Care *(Complete Airway Repositioning and Expansion)* and product-specific training for the use of our products and services. Revenue from such courses is not material at the present time, but our expectation is that increased training awareness of OSA and the promotion of our products and services will be enhanced by the Vivos Institute.

- ***The Airway Intelligence Service (AIS).*** This service provides a complete resource for VIPs to help simplify the diagnostic and appliance design matrix and expedite the treatment planning process. AIS is provided as part of the price of each appliance and is not a separate revenue stream.

- ***Billing Intelligence Services (BIS).*** This complete third-party billing solution includes a comprehensive integrated revenue cycle management software system that allows dentists to focus on running their practice and delivering the best care for their patients. This medical billing service generates recurring subscription fees from participating VIPs and independent dentists in the United States.

- ***AireO^2 Patient Management Software.*** This management software enables healthcare professionals to diagnose, treat and monitor patients with OSA and its related conditions more effectively. Developed in collaboration with Lyon Dental, AireO^2 contains features that enhance a VIP's billing services and practice management systems. AireO^2 is a complement to our BIS software system. In April 2021, we entered into an asset purchase agreement with Lyon Management and Consulting, LLC and its affiliates to acquire certain medical billing and practice management software, licenses and contracts, including the software underlying AireO2. The asset acquisition allows us to expand and enhance our current medical billing practice through our BIS division. The terms of the purchase include $0.2 million of cash and the issuance of a warrant to purchase 25,000 shares of our common stock at a price of $8.90 per share for three years. The vesting of the warrant is as follows: 5,000 shares vested immediately upon issuance of the warrant, 10,000 shares vest and become exercisable on April 14, 2022 and 10,000 shares vest and become exercisable on April 14, 2023.

- ***Medical Integration Division (MID).*** In late 2020, we launched our MID to assist VIP practices to establish clinical collaboration ties to local primary care physicians, sleep specialists, ear, nose a throat doctors (ENTs), cardiologists, pediatricians, pulmonologists and other healthcare providers who routinely see or treat patients with sleep and breathing disorders. The primary objective of our MID is to promote The Vivos Method to medical providers and thus facilitate the potential for more mild to moderate OSA patients gaining access to The Vivos Method while offering continuum of care. The MID seeks to fulfill that objective by meeting with VIP dentists and medical providers in their local areas to establish physician practices using the trademarked name "Pneusomnia Sleep Reimagined Center" (which we refer to as Pneusomnia Centers that are part of the Vivos MID). These independent medical practices will be managed by our company under a management and development agreement which pays us six (6%) percent of all net revenue from sleep-related services. We also collect a development fee for each clinic prior to opening establishing all operational protocols. We have built into our core MID business model a great degree of flexibility, such that elements of each Pneusomnia Center as described above may change and be adapted to local state laws and regulations, and entity formation laws as any such alterations do not violate any state or federal statutes or regulations. We believe our early market response from MID activities has been promising, and in March 2021 we announced the opening of the first Pneusomnia Center in Del Mar, California, and in May 2021, the second in Modesto, California, with plans to open additional Pneusomnia Centers in several other cities in the U.S. However, it remains too early to predict the eventual impact on our overall revenue. If successful, the MID is expected to enhance the overall practice level economics for independent VIP offices and generate additional lines of recurring revenue for us.

- ***MyoCorrect (Orofacial Myofunctional Therapy) Program.*** In March 2021, we introduced orofacial myofunctional therapy (or OMT) as a service that is part of The Vivos Method, under the name MyoCorrect. Through MyoCorrect, dentists enrolled in the VIP program will have access to trained therapists who provide OMT via telemedicine technology. This OMT therapy can be a component of obstructive sleep apnea treatment in conjunction with The Vivos Method which includes our Class II oral appliances and protocols. OMT, which is given by a certified OMT therapist, involves exercises and other techniques aimed at strengthening the tongue and orofacial muscles by teaching individuals how to engage the muscles to the appropriate position.

Our Competitive Strengths

We believe that The Vivos Method has numerous advantages that, taken together, set us apart from the competition and position us for success in the marketplace:

- ***Significant barriers to entry:*** We believe that third parties seeking to compete directly with us have significant barriers to entry for the following reasons: competitors must offer a treatment modality with similar features, capabilities, research support, FDA regulatory clearances, and successful clinical outcomes in the market; then establish a comprehensive educational training program featuring other clinical professionals with actual experience and success using that particular treatment modality to properly educate dentists on all clinical aspects of use with patients; then develop and promulgate the systems and best practices required to successfully integrate the treatment of dentofacial abnormalities and/or mild to moderate OSA and snoring using this novel treatment modality in a dental practice; then establish and provide, by recruitment and otherwise, ongoing clinical mentoring and support to independent dentists engaged in treating their patients for dentofacial abnormalities and/or mild to moderate OSA and snoring and related conditions (clinical mentors are limited and may be hard to find); and finally, assisting the dentists with case selection, case acceptance, patient financing, and medical insurance reimbursement. We believe we have strategically and effectively addressed each and every one of the aforementioned barriers to entry, and thus have created a novel and compelling single-source value proposition for dentists seeking to deliver OSA treatment to their patients.

- ***Vivos Method insurance reimbursement:*** Most major commercial insurance (and also Medicare for the mmRNA appliance, which we achieved during 2021), reimburse for our adult treatment in the United States. The average level of commercial payer reimbursement is approximately 50% (with coverage ranging from 5% to 70%), although medical insurance is never a guarantee of payment, and patient deductibles and policy restrictions will vary. Medicare reimbursement for the mmRNA appliance will vary by the Centers for Medicare and Medicaid Services (CMS) jurisdiction in the U.S.

- ***Body of published research and strong patient outcomes:*** Together with our network of trained dentists, we have developed a body of clinical and patient data over approximately ten years and an estimated 25,000 patients treated with our proprietary clinical protocols that demonstrates the safety, effectiveness, therapy adherence (patient compliance), and benefits of The Vivos Method for its registered and 510(k) cleared uses. The documented and reported benefits of treatment with The Vivos Method have been consistent across reports from independent dentists and have been highlighted in approximately 55 published studies, case reports, and articles, many of which have been peer reviewed. We believe this favorable data provides us with a significant competitive advantage and will continue to support increased adoption.

- ***First mover advantage:*** Our business model is the first to focus on dentists screening patients for mild to moderate OSA, referring patients to physicians for diagnosis, with the dentists then serving as the primary source of treatment using The Vivos Method for such patients.

- ***Differentiated products:*** To our knowledge, we believe only The Vivos Method offers a truly differentiated, non-invasive treatment option that actually works on a common root cause of OSA. We also believe that older oral appliances are typically less expensive, but do not reshape the upper airway like our appliances, and therefore require nightly use over a lifetime, and have a number of other disadvantages.

- ***Intellectual property portfolio and research and development capabilities*** We have a comprehensive patent portfolio to protect our intellectual property and technology, five design patents that expire between 2023 through 2029 and two utility patents expiring in 2029 and 2030. We own two Canadian patents and one European patent that has been validated in Belgium, Switzerland, Germany, Denmark, Spain, France, United Kingdom, Hungary, Italy and the Netherlands, all of which expire in 2029. We also have three pending utility patents. Our U.S. trademark portfolio consists of 10 registered marks and one pending trademark applications. Extensive online and in-person training, multiple touch point support systems, specific fabrication materials, customized appliance designs, and multi-disciplinary treatment protocols are all considered proprietary trade secrets and competitive advantages with no known counterparts.

- ***Extensive Training and Support Systems:*** We believe our extensive online and in-person clinical and business systems training program offered through The Vivos Institute is unmatched anywhere in dentistry and is a clear competitive strength that would be difficult to replicate.

- ***Targeted approach to market development*****:** We have established a systematic and scalable approach to actively and consistently engage with our primary target audience of U.S. and Canadian dentists. In addition, our MID is actively targeting physicians and other relevant healthcare providers in order to build awareness and collaborative patient options for independent VIP practices.

- ***Marketplace acceptance:*** Patient access to The Vivos Method at a VIP practice is becoming more readily available, and active VIP providers can now be found in almost all major U.S. cities and in many cities in Canada.

Sales and Marketing

We have established a methodical approach to market development which centers on active engagement directly with members of the medical community, including general dentists and medical doctors who treat dentofacial abnormalities and/or mild to moderate OSA and snoring, to educate them on The Vivos Method and its benefits. The goals of our sales and marketing efforts are (i) to secure new VIP dentists and provide them with the tools to treat patients with our products and (ii) more broadly educate the medical community regarding our products with a view towards expanding our number of VIPs as well as medical professionals who could refer patients to our VIPs for treatment.

We sell the VIP Program to dentists through a direct sales force that primarily targets general dentists in the United States and Canada. Our sales effort is developed through social media initiatives, and our new website with over 150 videos, and the production of over 350 new content creation projects. Our VIP program was developed to train independent dentists to identify and treat dental conditions that may be associated with mild to moderate sleep apnea. Our sales program to target medical doctors is our MID program, which was developed to assist VIP practices to establish clinical collaboration ties to local primary care physicians, sleep specialists, ENTs, pediatricians, pulmonologists and other healthcare professionals who routinely see or treat patients with sleep and breathing disorders.

In countries outside of North America we typically offer a modified training and support program at a lower cost. We currently have approximately 25 direct sales representatives in the United States and Canada. Our direct sales force engages in sales efforts and promotional activities focused on referring physicians, as well as directly to the over 200,000 professionally active general dentists in the United States and 20,000 general dentists in Canada.

Our current VIP sales organization is comprised of three teams consisting of:

- one *Enrollment Specialist*, who is the primary salesperson responsible for enrolling new VIPs;
- two *Enrollment Support Staff* members, who are responsible for organizing potential VIP appointments for the Enrollment Specialist;
- three *Business Development Associates*, who are responsible for cultivating new business leads which are referred to the Enrollment Support Staff;
- one *Outreach and Engagement Associate*, who is responsible for engaging with potential VIPs in our sales process with surveys and offers of online courses with the purpose of leads to be referred to the Enrollment Support Staff members; and
- one *Practice Advisory Onboarding Specialist*, who is responsible for onboarding new VIPs to our training programs.

Our MID sales organization is comprised of a Senior Vice President that leads the MID sales efforts and one Senior Director of Business Development. We plan on growing our MID sales organization by recruiting candidates that have extensive healthcare backgrounds, strong business development experience setting up physician owned medical facilities/practices and significant healthcare regulatory knowledge.

We utilize indirect and direct marketing channels to inform and educate dentists, medical doctors and healthcare professionals about The Vivos Method. Our indirect marketing channels include strategic partners, industry key opinion leaders, trade shows and our own clinical advisor network. In 2021, we made strides by establishing the following strategic partnerships aimed and broadening awareness of and selling efforts for The Vivos Method:

- In October 2021, we announced a new collaboration with Candid Care Co., a digital platform for oral healthcare, which that will seek to provide patients with a comprehensive, whole-mouth solution to diagnose and treat OSA in adult patients and provide orthodontic treatment from the same provider network. At the core of this collaboration, Vivos and Candid will market each company's products and areas of expertise to deliver a comprehensive sleep and oral health solution to patients in the United States and Canada. The focus of the collaboration will be Candid's CandidPro clear aligner for straightening teeth and the Vivos Method for treating OSA. The two companies will also share educational resources, training, and key opinion leaders to bridge the gap between airway health and orthodontic therapy.

  Our ongoing collaboration with Candid is still in the early and formative stages, primarily due to a major strategy change by Candid where they completely shut down their direct-to-consumer initiatives in order to focus entirely on their CandidPro model emphasizing active dentist participation and patient interaction. Now that Candid has made that transition, we fully expect to see an increase in alignment and close collaboration between our two companies. The emphasis will be on sharing provider lists, dentist prospects, DSO affiliations, and jointly developing future clinical products. We currently have bi-weekly conference calls between respective company senior management and expect that to continue.

- In August 2021, we announced a cooperative relationship with Empower Sleep, a San Bernardino, California-based company empowering patients with affordable, accessible and personalized telemedicine sleep care, to provide critical diagnostic and medical consultation services to people across North America who suffer from OSA. Together, Vivos and Empower Sleep plan to leverage each company's core technologies to provide a user-friendly platform with personalized insights for patients who are being screened for OSA by North American dentists and other healthcare providers.

Empower Sleep spent most of 2021 organizing and obtaining medical licensure throughout the U.S. Currently, Empower Sleep is fully licensed to practice medicine in approximately 40 states and expect to be in all 50 states by the end of the second quarter of 2022. Dr. Sahil Chopra is the primary sleep specialist and owner of Empower Sleep. He regularly speaks at Vivos events and has largely organized his company in a manner that best serves our VIPs and their patients. While much progress has been made to fully operationalize the Vivos/Empower Sleep dentist and patient interactions, we believe some work remains to smooth out the inefficiencies and normal start-up risks. We believe our two companies work very well together and share a mutual purpose and mission.

Our direct marketing channels include outreach to prospective VIPs using digital advertising platforms including Facebook and Google ad placements. The objective of our indirect and direct marketing efforts are to bring dentists, medical doctors and healthcare professionals to our educational and training websites to learn about OSA and its treatment alternatives.

We further believe our dentist and medical doctor marketing efforts have been effective in facilitating contact via our Vivos introduction and online training webinars, despite significant headwinds throughout our core customer base, mostly driven by COVID-19 Delta and Omicron variant resurgences in the middle and latter part of the year.

Potential Economics for Trained VIP Clinicians

Dentists that enroll in our VIP program have the potential for compelling economics. The actual incidence of dental patients with OSA will vary, but our conservative estimate would suggest that the average dental practice sees 400-500 adult patients a year with a high risk of suffering from obstructive sleep apnea. Using these demographic figures, the economic potential per dentist may be calculated, based on a retail adult case fee of approximately $9,000, fully burdened VIP provider costs of approximately $3,000, and net profit of approximately $6,000, to be over $3.3 million in annual gross revenue potential annually with over $2.4 million in potential net profit. We believe, based on our experience, that dentists have seen accretive economic additions to their practices by utilizing The Vivos Method, and thus participation in the VIP program can likely add to the dentist's take-home income.

In terms of continuing training, our sales and clinical advisory dentists conduct training primarily in a highly personalized, deep immersion workshop format at our Vivos Institute. The key topics covered in training include case selection, clinical diagnosis, treatment planning, appliance design, adjunctive therapies, information on our productions and services, guidance on pricing, case acceptance, instruction on insurance reimbursement protocols and interacting with our proprietary software system and the many other features of our website. We present our training material in a manner we believe to be superior to most other dental training and experience, including preparatory online courses, didactic lectures, hands-on training, specialized small group breakout sessions, and post training technical support from assigned mentors. As a result, we are able to complete the initial training workshops, both online and in person, typically within just 15 days spread out over several weeks. Our success in training approximately 1,450 dentists confirms our belief that training represents a minimal barrier to adoption for most dentists.

Below is an illustrative model depicting the total additional revenue a dentist might receive by treating patients with The Vivos Method. The potential patients with dentofacial abnormalities and/or mild to moderate OSA is determined by using a calculation that results in a conservative estimate that 30% of patients of a dental practice patient may suffer from OSA (according to a 2019 article published in *Chest Physician*). The revenue treatment fee is estimated at $9,000 per patient. This illustration helps to explain why a dentist might want to become a trained VIP and use The Vivos Method.

Number of Active Patients in Typical Dental Practice	Potential Patients with OSA	Potential Additional Revenue for Dentist
1,250	375	$ 3,375,000
1,500	450	4,050,000
1,750	525	4,725,000
2,000	600	5,400,000
2,250	675	6,075,000

To facilitate the adoption of The Vivos Method, we market the VIP Program, and as part of that offering, we often partner with equipment manufacturers to bundle training and equipment into a turn-key program financed by third party lenders for those dental practices who need to purchase additional equipment. The VIP Program fees are also often financed by third party lenders separate from any equipment purchases. Loan terms and payments will vary depending on the doctor's credit, the interest rate, the amount financed, and the term of the loan. Generally, payments on such financing range from about $600 to $2,500 per month.

Insurance Reimbursement

Our mRNA appliance® and mmRNA appliance® are custom fabricated appliances to treat mild to moderate OSA and snoring in adults. The mRNA and mmRNA can be billed in and out of network to most commercial payers under the E0486 CPT code. The E0486 is reimbursable by many major commercial medical payers following a medical diagnosis of OSA. Level of reimbursement is approximately 50% (ranging from 5% to 70%), although medical insurance is never a guarantee of payment, and patient deductibles and policy limitations may vary. A verification of benefits is required for all medical policies to check for validity of CPT code E0486 and oral appliance therapy (OAT). Pre-authorization may be required for reimbursement. Pre-Authorization requirements may vary based on the payer policies and patient's insurance coverage. Although many patients pay for treatment out of pocket on a fee for service basis, the availability of health insurance coverage is an important consideration for many patients who desire treatment in The Vivos Method. All medical policies have different reimbursement policies which may affect availability of reimbursement.

VIPs typically remain out of network with commercial health insurance payers, but this depends on the individual practice and the commercial payer guidelines in each state. As out of network providers, dentists can set their own fees and balance bill the patient for the cost of care not covered by the patient's health insurance. The American Medical Association will provide fee ranges for all billable CPT codes. A dentist must set their own fees for the CPT codes billed in their office that are within their scope of practice.

Our mRNA appliance® and our DNA appliance are not covered by Medicare or Medicaid as they do not meet the approved design criteria by CMS. We made modifications to the mRNA appliance® to meet CMS criteria for the billing code E0486 to Medicare. These slight modifications of the mRNA appliance® led to the creation of a new FDA cleared device, the mmRNA appliance® (*Modified Mandibular Repositioning Nighttime Appliance*). In February 2021, we submitted a 510(k) for Class II clearance to the FDA for the mmRNA appliance with indications to treat mild to moderate OSA and snoring in adults, which was approved by FDA in August 2021. In December 2021, we received acceptance from a Centers for Medicare & Medicaid Services Pricing, Data Analysis and Coding ("PDAC") contractor for our mmRNA applicable for treating mild to moderate OSA and snoring in adults. This acceptance places the mmRNA device on the PDAC list of oral appliances covered by and billable to Medicare, making the benefits of the mmRNA device available to millions of Medicare beneficiaries. Notwithstanding this important achievement, in general we have not found the lack of inclusion on the current CMS Medicare list of approved sleep appliances to hinder market distribution or acceptance due to the fact that most dentists who work with The Vivos Method are out of network with commercial payers and do not typically file for reimbursement under Medicare.

We have seen an increase in the ability for reimbursement for our other FDA registered oral appliances such as the DNA appliance and the Vivos Guides. These oral appliances are being pre-authorized and billed under an undefined CPT code only when medical necessity is present and documented properly. Pre-authorization with medical director review is required with a "letter of medical necessity" (LMN) to gain possible medical reimbursement. A dentist billing an undefined CPT code for a Class I or Class II oral appliance must proceed with caution. Billing an undefined CPT code for OAT must be supported with documented medical necessity and is reviewed by the medical director at the payor before being submitted for possible reimbursement. Typically, the dentist writes an LMN to explain the medical necessity and the patient's request for oral appliance therapy and submits the LMN for review to the medical directors at the payor. The plan medical directors will then review the LMN, including any dentofacial abnormalities, CT images, comorbidities, and any medical conditions the patient has be diagnosed with by a medical doctor. This documentation is how the dentist establishes medical necessity. Once pre-authorization is gained, then OAT can be billed for a possible reimbursement from the medical payor. A dentist typically can gain reimbursement for OAT by the medical insurance if the undefined code is valid and billable under their policy and there is medical necessity present, supported, and documented.

Published Research

There are several studies in the medical literature on upper airway remodeling in pathologic conditions such as asthma, chronic obstructive pulmonary disease and similar conditions. In contrast, there is a dearth of studies that have documented pneumatization and physiologic upper airway remodeling. Advances in 3D digital technology, as well as an increased understanding of the human genome and epigenetics, has allowed us to make further advances in the understanding of dentofacial phenomena. For example, while it was believed that sutures undergo closure in early adulthood, according to published research, it is now thought that populations of stem cells may persist to permit continued growth and development. Using this premise, the midfacial bone volume can be increased surgically or non-surgically. Since the roof of the mouth is the floor of the nose, the volume of the nasal airway can also be increased surgically or non-surgically. Therefore, using our patented, non-surgical protocols we targeted oral conditions and upper airways to address dentofacial abnormalities and/or mild to moderate OSA and snoring. Using various assessment techniques, we found surface area, volumetric and functional changes of the upper airway.

Since 2009, our technology has been the subject of approximately 55 peer-reviewed articles in the medical, dental and orthodontic literature. Of the 55 articles, 27 of these are journal papers, with Dr. G. Dave Singh, our founder and former Chief Medical Officer, as first author on 22 of these papers. Of the 27 journal papers, 17 of these articles describe the studies that examine the impact of our technology and protocols on the AHI scores of patients with varying degrees of OSA as described in "Overview" above. In addition, over 25 conference papers have been published as abstracts, with Dr. Singh as first author on 20 of these conference papers. Additionally, there were 19 independent dentists and five different sleep physicians are co-authors on these publications as well. The results published in these case reports and articles, together with patient-reported outcomes, have illustrated that The Vivos Method therapy can provide a significant change in the severity of patients' with dentofacial abnormalities and/or mild to moderate OSA and snoring (as measured by industry standard indices such as the AHI, among others), improvement in oral conditions, sleep-related quality of life, reduction in snoring, high patient compliance rates and a strong safety profile.

Intellectual Property

To establish and protect our proprietary rights, we rely on a combination of patents, trademarks, copyrights and trade secrets, including know-how, license agreements, confidentiality procedures, non-disclosure agreements with third parties, employee disclosure and invention assignment agreements, and other contractual rights. Our intellectual property is important in achieving and maintaining our position in the market. We currently own five design patents that expire between 2023 through 2029 and two utility patents expiring in 2029 and 2030. We also own two Canadian patents and a European patent that has been validated in Belgium, Switzerland, Germany, Denmark, Spain, France, United Kingdom, Hungary, Italy and the Netherlands, all of which expire in 2029. Our U.S. trademark portfolio consists of ten registered marks and one pending trademark application. Extensive online and in-person training, multiple touch point support systems, specific fabrication materials, customized appliance designs, and multi-disciplinary treatment protocols are all considered proprietary trade secrets and competitive advantages with no known counterparts.

FDA Regulatory Status

The Vivos Method offers treatment protocol that uses nonsurgical, noninvasive, and cost-effective oral appliance technology prescribed by trained dentists and medical professionals to treat dentofacial abnormalities and/or mild to moderate OSA and snoring. The Vivos Method includes a customized treatment plan that may begin with a simple and easy at-home sleep apnea screening using proprietary HST technology from SleepImage. We offer two Class II devices cleared by the FDA (*mRNA and mmRNA*) and one Class I device registered with the FDA (DNA). We offer our own pre-formed Vivos Guides. The regulatory status of our products is as follows:

- Our mmRNA (Pat.Pend.) appliance has a 510(k) clearance from the FDA as a Class II medical device for the treatment of jaw repositioning, snoring and mild to moderate OSA in adults.

- Our mRNA appliance® has 510(k) clearance from the FDA as a Class II medical device for the treatment of snoring and mild to moderate OSA in adults.

- The DNA appliance® is an FDA-registered product for expansion and is currently used by Vivos-trained clinicians. We instruct all dentists prescribing the DNA appliance about the device's approved indications of use and of the fact that the DNA appliance is a Class I FDA registered oral appliance. Dentists, as licensed clinicians within the scope of their practice, are free to diagnose, treat and prescribe the appropriate oral appliance therapy as they see fit, including uses which might be "off label", based on their professional judgement. Given the fact that our dentists regularly prescribe the DNA appliance to treat conditions closely associated with OSA, we do not believe a failure to receive FDA Class II clearance would materially impact our results or financial condition. Any potential consequences of off-label use of the DNA appliance are the responsibility of the treating dentist; however, we may face consequences related to such off-label use. See "*Risk Factors— 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."*

- The Vivos Guides are an FDA-registered product for orthodontic tooth positioning. In October 2021, we announced that results from a peer-reviewed, published study by an independent dentist found a significant reduction of tooth decay in pediatric patients after undergoing treatment using our Vivos Guides.

We are conducting two separate Western Copernicus Group Institutional Review Board (WCG IRB) approved pediatric clinical trials with eight private dental sites around the country. The purpose of the first study is to evaluate the safety and efficacy of an intraoral device (the DNA) to reduce sleep-disordered breathing (SDB) in children, including: snoring, mild to moderate obstructive sleep apnea (OSA), and Upper Airway Resistance Syndrome (UARS). The child subjects enrolled in this study will be using the DNA appliance to correct orthodontic issues. They will also present with midfacial hypoplasia suitable for palatal expansion. During orthodontic treatment and palatal expansion, the device will be studied to determine whether it can also reduce symptoms of sleep disordered breathing in children. The study will recruit pediatric subjects who have already elected to utilize the study device for their orthodontic treatment. If they meet the inclusion and exclusion criteria, then they will be included in the study. The purpose of the second study is to evaluate the safety and efficacy of an intraoral device (the Vivos Grow and/or Vivos Way appliances) to reduce sleep-disordered breathing (SDB) in children, including: snoring, mild to moderate obstructive sleep apnea (OSA), and Upper Airway Resistance Syndrome (UARS). The child subjects enrolled in this study will be using the Vivos Grow/Vivos Way appliance to correct orthodontic issues. They will also present with midfacial hypoplasia suitable for palatal expansion. During orthodontic treatment and palatal expansion, the devices will be studied to determine whether they can also reduce symptoms of sleep disordered breathing in children. The study will recruit pediatric subjects who have already elected to utilize the study device for their orthodontic treatment. If they meet the inclusion and exclusion criteria they can be included in the study. Upon completion of these WIRB pediatric clinical trials (expected to be completed in the next 6 to 12 months), we plan to submit two separate 510(k) applications to the FDA requesting pediatric clearances and indications of use for the DNA appliance® as well as the Vivos Guides.

Our mRNA appliance® and mmRNA appliance® are cleared by the FDA as Class II sleep appliances to treat mild to moderate OSA and snoring in adults. Patients undergoing treatment are seeing improvement in the said cleared indications of use, but clinicians have also reported that they are seeing other comorbidities and medical conditions improve due to treatment. These appliances (which are central to The Vivos Method) and other Vivos appliances are made available to trained clinicians who exercise their independent clinical judgment with respect to their use and suitability as a part of an overall treatment protocol created for each individual patient.

In September 2017 our subsidiary, BMS, was the subject of its first routine FDA audit. That audit resulted in findings that required BMS to remediate certain deficiencies such as: (i) inadequate documentation of certain FDA-required procedures (i) not keeping certain records and materials in paper format and in triplicate, and (iii) the use of certain descriptive words and phrases on its website and in marketing materials that were not approved in advance by FDA. We immediately hired a highly qualified FDA consultant and legal counsel with FDA expertise to assist BMS in preparing both a written response and a plan for regaining and maintaining compliance with FDA regulations and guidelines. In good faith, and based on documents provided by BMS, we believed BMS had filed its response to the original audit in a timely manner with FDA which was due on [ ]. However, in January 2018 BMS received a request for a response to an FDA Warning Letter (the "Warning Letter") that had been posted online at the FDA website. The Warning Letter stated that BMS failed to reply in a timely manner and address the findings of the September audit. We believed that we had filed out response to the FDA on September 27, 2017. The local BMS office in Portland, Oregon was closed down as of September 30, 2017 pursuant to a share exchange agreement which made BMS a subsidiary of our company (and which transaction was accounted for as a merger as disclosed in the consolidated financial statements). This transaction was disclosed to the FDA, and neither we nor BMS ever received any further notices from FDA after September 2017.

Immediately upon becoming aware of the miscommunication and deficiency, we notified the FDA of the error and provided the FDA with full documentation of our substantial efforts to fully comply with FDA rules and regulations. The FDA completed a second audit in April 2018, which examined our responses to the initial deficiencies and our compliance plan. We believe that this matter has been satisfactorily resolved, although no definitive statement to that effect has been made by FDA, nor has the Warning Letter been taken down from the FDA website. The FDA also audited our company (then known as Vivos BioTechnologies, Inc.) and issued one minor observation, to which we have responded and addressed.

In August of 2020, we underwent our 2-year FDA regulatory inspection. This inspection resulted in our receipt of an FDA Form 483 with two observations. These observations were corrected and responded to according the Code of Federal Regulations. Upon the review of the 483 responses, the FDA delivered a letter to us requesting additional information. We responded to the letter, and thereafter learned that the FDA was satisfied with our responses.

Manufacturing and Supply

We rely on third-party suppliers and manufacturers on a per order, or per item basis. Outsourcing manufacturing reduces our need for capital investment and reduces operational expenses. Additionally, outsourcing provides expertise and capacity necessary to scale up or down based on demand for our appliances. We select our manufacturing labs so we can ensure that our appliances are safe and effective, adhere to all applicable regulations, are of the highest quality, and meet our supply needs. We also rely on third-party carriers and freight forwarders for product shipments, including shipments to and from our manufactures' distribution facilities and customer distribution facilities.

Our Ongoing Clinical Research

We are committed to ongoing research and development, and we intend to invest in our business to further improve our products and clinical outcomes, increase patient acceptance and comfort and broaden the patient population that can benefit from The Vivos Method.

- ***Protocol approved February 2021 – Biomimetic oral appliance therapy (BOAT) for the treatment of mild to moderate OSA in adults (March 2022 renamed* "Daytime Nighttime Appliance (DNA) therapy for the treatment of Obstructive Sleep Apnea (OSA)").** The aim of this study is to investigate structural and functional effects of the treatment protocol using the DNA appliance® in the treatment of mild to moderate OSA in adults. This study will test the hypothesis that treatment of the upper airway associated with functional improvements of sleep parameters in adults with mild to moderate OSA.
- ***Commenced January 2019 – Treatment of SDB with an intraoral device in a pediatric population.*** Approved by WCG IRB as non-significant controlled clinical trials, we are conducting 2 separate clinical trials to evaluate the safety and efficacy of the DNA appliance® and the Vivos Guides (which we call the Vivos Grow and Vivos Way appliances) to reduce SDB in children, including snoring, mild to moderate OSA, and UARS. The WCG IRB is an independent Institutional Review Board located in Olympia, Washington that provides services for academic and non-academic institutions. WCG IRB is accredited by the Association for the Accreditation of Human Research Protection Programs. (AAHRPP) Clinical outcomes: Pediatric Sleep Questionnaire, reduction in sleep apnea and UARS using the AHI, Epworth Sleepiness Scale for Children and Adolescents, and changes in upper airway volume.

Government Regulation

Our products and our operations are subject to extensive regulation by the FDA and other federal and state authorities in the United States, as well as comparable authorities in the European Economic Area ("EEA"). Our products are subject to regulation as medical devices under the Federal Food, Drug, and Cosmetic Act, or FDCA, as implemented and enforced by the FDA. The FDA regulates the development, design, non-clinical and clinical research, manufacturing, safety, efficacy, labeling, packaging, storage, installation, servicing, recordkeeping, premarket clearance or approval, import, export, adverse event reporting, advertising, promotion, marketing and distribution, and import and export of medical devices to ensure that medical devices distributed domestically are safe and effective for their intended uses and otherwise meet the requirements of the FDCA.

In addition to U.S. regulations, we are subject to a variety of regulations in the EEA governing clinical trials and the commercial sales and distribution of our products. Whether or not we have or are required to obtain FDA clearance or approval for a product, we will be required to obtain authorization before commencing clinical trials and to obtain marketing authorization or approval of our products under the comparable regulatory authorities of countries outside of the United States before we can commence clinical trials or commercialize our products in those countries. The approval process varies from country to country and the time may be longer or shorter than that required for FDA clearance or approval.

FDA Premarket Clearance and Approval Requirements

Unless an exemption applies, each medical device commercially distributed in the United States requires either FDA clearance of a 510(k) premarket notification or pre-market approval (PMA). Under the FDCA, medical devices are classified into one of three classes—Class I, Class II or Class III—depending on the degree of risk associated with each medical device and the extent of manufacturer and regulatory control needed to ensure its safety and effectiveness. Class I includes devices with the lowest risk to the patient and are those for which safety and effectiveness can be assured by adherence to the FDA's General Controls for medical devices, which include compliance with the applicable portions of the QSR, facility registration and product listing, reporting of adverse medical events, and truthful and non-misleading labeling, advertising, and promotional materials. Class II devices are subject to the FDA's General Controls, and special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. These special controls can include performance standards, post-market surveillance, patient registries and FDA guidance documents. While most Class I devices are exempt from the 510(k) premarket notification requirement, manufacturers of most Class II devices are required to submit to the FDA a premarket notification under Section 510(k) of the FDCA requesting permission to commercially distribute the device. The FDA's permission to commercially distribute a device subject to a 510(k) premarket notification is generally known as 510(k) clearance. Under the 510(k) process, the manufacturer must submit to the FDA a premarket notification demonstrating that the device is "substantially equivalent" to either a device that was legally marketed (for which the FDA has not required a PMA submission) prior to May 28, 1976, the date upon which the Medical Device Amendments of 1976 were enacted, or another commercially available device that was cleared to through the 510(k) process. The FDA has 90 days from the date of the pre-market equivalence acceptance to authorize or decline commercial distribution of the device. However, similar to the PMA process, clearance may take longer than this three-month window, as the FDA can request additional data. If the FDA resolves that the product is not substantially equivalent to a predicate device, then the device acquires a Class III designation, and a PMA must be approved before the device can be commercialized.

The Vivos Guides are registered with the FDA as Class I devices for orthodontic tooth positioning. The DNA appliance® is registered with the FDA as a Class I device for expansion and is currently used by Vivos-trained clinicians accordingly.

Devices deemed by the FDA to pose the greatest risks, such as life-sustaining, life-supporting or some implantable devices, or devices that have a new intended use, or use advanced technology that is not substantially equivalent to that of a legally marketed device, are placed in Class III, requiring approval of a PMA. Some pre-amendment devices are unclassified but are subject to the FDA's premarket notification and clearance process in order to be commercially distributed. We do not have any Class III devices.

PMA Pathway

Class III devices require PMA approval before they can be marketed although some pre-amendment Class III devices for which the FDA has not yet required a PMA are cleared through the 510(k) process. The PMA process is more demanding than the 510(k) premarket notification process. In a PMA application, the manufacturer must demonstrate that the device is safe and effective, and the PMA application must be supported by extensive data, including data from preclinical studies and human clinical trials. The PMA must also contain a full description of the device and its components, a full description of the methods, facilities and controls used for manufacturing, and proposed labeling. Following receipt of a PMA application, the FDA determines whether the application is sufficiently complete to permit a substantive review. If the FDA accepts the application for review, it has 180 days under the FDCA to complete its review of a PMA application, although in practice, the FDA's review often takes significantly longer, and can take up to several years. An advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. The FDA may or may not accept the panel's recommendation. In addition, the FDA will generally conduct a preapproval inspection of the applicant or its third-party manufacturers.

The FDA will approve the new device for commercial distribution if it determines that the data and information in the PMA application constitute valid scientific evidence and that there is reasonable assurance that the device is safe and effective for its intended use(s). The FDA may approve a PMA application with post-approval conditions intended to ensure the safety and effectiveness of the device, including, among other things, restrictions on labeling, promotion, sale and distribution, and collection of long-term follow-up data from patients in the clinical study that supported a PMA approval or requirements to conduct additional clinical studies post-approval. The FDA may condition a PMA approval on some form of post-market surveillance when deemed necessary to protect the public health or to provide additional safety and efficacy data for the device in a larger population or for a longer period of use. In such cases, the manufacturer might be required to follow certain patient groups for a number of years and to make periodic reports to the FDA on the clinical status of those patients. Failure to comply with the conditions of approval can result in material adverse enforcement action, including withdrawal of the approval.

Certain changes to an approved device, such as changes in manufacturing facilities, methods, or quality control procedures, or changes in the design performance specifications, which affect the safety or effectiveness of the device, require submission of a new PMA application or a PMA supplement. PMA supplements often require submission of the same type of information as a PMA application, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA application and may not require as extensive clinical data or the convening of an advisory panel. Certain other changes to an approved device require the submission of a new PMA application, such as when the design change causes a different intended use, mode of operation, and technical basis of operation, or when the design change is so significant that a new generation of the device will be developed, and the data that were submitted with the original PMA application are not applicable for the change in demonstrating a reasonable assurance of safety and effectiveness.

Clinical Trials

Clinical trials are almost always required to support a PMA application and are sometimes required to support a 510(k) submission. All clinical investigations of investigational devices to determine safety and effectiveness must be conducted in accordance with the FDA's investigational device exemption, or IDE, regulations which govern investigational device labeling, prohibit promotion of the investigational device, and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. If the device presents a "significant risk" to human health, as defined by the FDA, the FDA requires the device sponsor to submit an IDE application to the FDA, which must become effective prior to commencing human clinical trials. A significant risk device is one that presents a potential for serious risk to the health, safety, or welfare of a patient and either is implanted, used in supporting or sustaining human life, substantially important in diagnosing, curing, mitigating or treating disease or otherwise preventing impairment of human health, or otherwise presents a potential for serious risk to a subject. An IDE application must be supported by appropriate data, such as animal and laboratory test results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE will automatically become effective 30 days after receipt by the FDA unless the FDA notifies us that the investigation may not begin. If the FDA determines that there are deficiencies or other concerns with an IDE for which it requires modification, the FDA may require a response on such deficiencies or permit a clinical trial to proceed under a conditional approval.

In addition, the study must be approved by, and conducted under the oversight of, an Institutional Review Board, or IRB, for each clinical site. The IRB is responsible for the initial and continuing review of the IDE, and may pose additional requirements for the conduct of the study. If an IDE application is approved by the FDA and one or more IRBs, human clinical trials may begin at a specific number of investigational sites with a specific number of patients, as approved by the FDA. If the device presents a non-significant risk to the patient, a sponsor may begin the clinical trial after obtaining approval for the trial by one or more IRBs without separate approval from the FDA, but must still follow abbreviated IDE requirements, such as monitoring the investigation, ensuring that the investigators obtain informed consent, and labeling and record-keeping requirements. Acceptance of an IDE application for review does not guarantee that the FDA will allow the IDE to become effective and, if it does become effective, the FDA may or may not determine that the data derived from the trials support the safety and effectiveness of the device or warrant the continuation of clinical trials. An IDE supplement must be submitted to, and approved by, the FDA before a sponsor or investigator may make a change to the investigational plan that may affect its scientific soundness, study plan or the rights, safety or welfare of human subjects.

During a study, the sponsor is required to comply with the applicable FDA requirements, including, for example, trial monitoring, selecting clinical investigators and providing them with the investigational plan, ensuring IRB review, adverse event reporting, record keeping and prohibitions on the promotion of investigational devices or on making safety or effectiveness claims for them. The clinical investigators in the clinical study are also subject to FDA regulations and must obtain patient informed consent, rigorously follow the investigational plan and study protocol, control the disposition of the investigational device, and comply with all reporting and recordkeeping requirements. Additionally, after a trial begins, we, the FDA or the IRB could suspend or terminate a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits.

Post-market Regulation

After a device is cleared or approved for marketing, numerous and pervasive regulatory requirements continue to apply. These include:

- establishment registration and device listing with the FDA;
- QSR requirements, which require manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation, and other quality assurance procedures during all aspects of the design and manufacturing process;
- labeling and marketing regulations, which require that promotion is truthful, not misleading, fairly balanced and provide adequate directions for use and that all claims are substantiated, and also prohibit the promotion of products for unapproved or off-label uses and impose other restrictions on labeling; FDA guidance on off-label dissemination of information and responding to unsolicited requests for information;
- the federal Physician Sunshine Act and various state and foreign laws on reporting remunerative relationships with health care customers;
- the federal Anti-Kickback Statute (and similar state laws) prohibiting, among other things, soliciting, receiving, offering or providing remuneration intended to induce the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as Medicare or Medicaid. A person or entity does not have to have actual knowledge of this statute or specific intent to violate it to have committed a violation;
- the federal False Claims Act (and similar state laws) prohibiting, among other things, knowingly presenting, or causing to be presented, claims for payment or approval to the federal government that are false or fraudulent, knowingly making a false statement material to an obligation to pay or transmit money or property to the federal government or knowingly concealing, or knowingly and improperly avoiding or decreasing, an obligation to pay or transmit money to the federal government. The government may assert that claim includes items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the false claims statute;
- clearance or approval of product modifications to 510(k)-cleared devices that could significantly affect safety or effectiveness or that would constitute a major change in intended use of one of our cleared devices, or approval of a supplement for certain modifications to PMA devices;
- medical device reporting regulations, which require that a manufacturer report to the FDA if a device it markets may have caused or contributed to a death or serious injury, or has malfunctioned and the device or a similar device that it markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur;

- correction, removal and recall reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health;

- complying with the new federal law and regulations requiring Unique Device Identifiers (UDI) on devices and also requiring the submission of certain information about each device to the FDA's Global Unique Device Identification Database (GUDID);

- the FDA's recall authority, whereby the agency can order device manufacturers to recall from the market a product that is in violation of governing laws and regulations; and

- post-market surveillance activities and regulations, which apply when deemed by the FDA to be necessary to protect the public health or to provide additional safety and effectiveness data for the device.

We may be subject to similar foreign laws that may include applicable post-marketing requirements such as safety surveillance. Our manufacturing processes are required to comply with the applicable portions of the quality system regulation ("QSR"), which cover the methods and the facilities and controls for the design, manufacture, testing, production, processes, controls, quality assurance, labeling, packaging, distribution, installation, and servicing of finished devices intended for human use. The QSR also requires, among other things, maintenance of a device master file, device history file, and complaint files. As a manufacturer, our facilities, records, and manufacturing processes are subject to periodic scheduled or unscheduled inspections by the FDA. Our failure to maintain compliance with the QSR or other applicable regulatory requirements could result in the shut-down of, or restrictions on, our manufacturing operations and the recall or seizure of our products. The discovery of previously unknown problems with any of our products, including unanticipated adverse events or adverse events of increasing severity or frequency, whether resulting from the use of the device within the scope of its clearance or off-label by a physician in the practice of medicine, could result in restrictions on the device, including the removal of the product from the market or voluntary or mandatory device recalls or a public warning letter that could harm both our reputation and sales. Any potential consequences of off-label use of the DNA appliance are the responsibility of the treating independent dentist; however, we may face consequences related to such off-label use. See "*Risk Factors— 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."*

The FDA has broad regulatory compliance and enforcement powers. If the FDA determines that we failed to comply with applicable regulatory requirements, it can take a variety of compliance or enforcement actions, which may result in any of the following sanctions:

- warning letters, untitled letters, fines, injunctions, consent decrees and civil penalties;
- recalls, withdrawals, or administrative detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying requests for 510(k) marketing clearance or PMA approvals of new products or modified products;
- withdrawing 510(k) clearances or PMAs that have already been granted;
- refusal to grant export or import approvals for our products; or
- criminal prosecution.

Regulation of Medical Devices in the EEA

There is currently no premarket government review of medical devices in the EEA (which is comprised of the 28 Member States of the EU plus Norway, Liechtenstein and Iceland). However, all medical devices placed on the market in the EEA must meet the relevant essential requirements laid down in Annex I of Directive 93/42/EEC concerning medical devices, or the Medical Devices Directive. There is also a directive specifically addressing Active Implantable Medical Devices (Directive 90/385/EEC). The most fundamental essential requirement is that a medical device must be designed and manufactured in such a way that it will not compromise the clinical condition or safety of patients, or the safety and health of users and others. In addition, the device must achieve the performances intended by the manufacturer and be designed, manufactured and packaged in a suitable manner. The European Commission has adopted various standards applicable to medical devices. These include standards governing common requirements, such as sterilization and safety of medical electrical equipment, and product standards for certain types of medical devices. There are also harmonized standards relating to design and manufacture. While not mandatory, compliance with these standards is viewed as the easiest way to satisfy the essential requirements as a practical matter. Compliance with a standard developed to implement an essential requirement also creates a rebuttable presumption that the device satisfies that essential requirement.

To demonstrate compliance with the essential requirements laid down in Annex I to the Medical Devices Directive, medical device manufacturers must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. Conformity assessment procedures require an assessment of available clinical evidence, literature data for the product and post-market experience in respect of similar products already marketed. Except for low-risk medical devices (Class I non-sterile, non-measuring devices), where the manufacturer can self-declare the conformity of its products with the essential requirements (except for any parts which relate to sterility or metrology), a conformity assessment procedure requires the intervention of a "Notified Body". Notified Bodies are often separate entities and are authorized or licensed to perform such assessments by government authorities. The Notified Body would typically audit and examine a product's technical dossiers and the manufacturers' quality system. If satisfied that the relevant product conforms to the relevant essential requirements, the Notified Body issues a certificate of conformity, which the manufacturer uses as a basis for its own declaration of conformity. The manufacturer may then apply the CE Mark to the device, which allows the device to be placed on the market throughout the EEA. Once the product has been placed on the market in the EEA, the manufacturer must comply with requirements for reporting incidents and field safety corrective actions associated with the medical device.

In order to demonstrate safety and efficacy for their medical devices, manufacturers must conduct clinical investigations in accordance with the requirements of Annex X to the Medical Devices Directive, Annex 7 of the Active Implantable Medical Devices Directive, and applicable European and International Organization for Standardization standards, as implemented or adopted in the EEA member states. Clinical trials for medical devices usually require the approval of an ethics review board and approval by or notification to the national regulatory authorities. Both regulators and ethics committees also require the submission of serious adverse event reports during a study and may request a copy of the final study report.

On April 5, 2017, the European Parliament passed the Medical Devices Regulation (Regulation 2017/745), which repeals and replaces the EU Medical Devices Directive and the Active Implantable Medical Devices Directive. Unlike directives, which must be implemented into the national laws of the EEA member States, the regulations would be directly applicable, i.e., without the need for adoption of EEA member State laws implementing them, in all EEA member States and are intended to eliminate current differences in the regulation of medical devices among EEA member States. The Medical Devices Regulation, among other things, is intended to establish a uniform, transparent, predictable and sustainable regulatory framework across the EEA for medical devices and ensure a high level of safety and health while supporting innovation. The Medical Devices Regulation will however only become applicable three years after publication (in 2020). Once applicable, the new regulations will among other things:

- strengthen the rules on placing devices on the market and reinforce surveillance once they are available;
- establish explicit provisions on manufacturers' responsibilities for the follow-up of the quality, performance and safety of devices placed on the market;
- improve the traceability of medical devices throughout the supply chain to the end-user or patient through a unique identification number;
- set up a central database to provide patients, healthcare professionals and the public with comprehensive information on products available in the EU; and
- strengthened rules for the assessment of certain high-risk devices, such as implants, which may have to undergo an additional check by experts before they are placed on the market.

We are subject to regulations and product registration requirements in many foreign countries in which we may sell our products, including in the areas of:

- design, development, manufacturing and testing;
- product standards;
- product safety;
- product safety reporting;
- marketing, sales and distribution;
- packaging and storage requirements;
- labeling requirements;
- content and language of instructions for use;
- clinical trials;
- record keeping procedures;
- advertising and promotion;
- recalls and field corrective actions;
- post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury;
- import and export restrictions;
- tariff regulations, duties and tax requirements;
- registration for reimbursement;

- necessity of testing performed in country by distributors for licensees; and
- the time required to obtain clearance required by foreign countries may be longer or shorter than that required for FDA clearance, and requirements for licensing a product in a foreign country may differ significantly from FDA requirements.

The EU Medical Devices Regulation became effective in May 2020. The revised regulation includes further controls and requirements on the following activities:

- high level of request for premarket clinical evidence for high-risk devices;
- increased scrutiny of technical files for implantable devices;
- monitoring of notified bodies, by independent auditors;
- increased requirements regarding vigilance and product traceability (specifically related to labeling requirements); and
- increased regulation for non-traditional roles such as importer and distributor.

Federal, State and Foreign Fraud and Abuse and Physician Payment Transparency Laws

In addition to FDA restrictions on marketing and promotion of drugs and devices, other federal and state laws restrict our business practices. These laws include, without limitation, foreign, federal, and state anti-kickback and false claims laws, as well as transparency laws regarding payments or other items of value provided to healthcare providers.

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind to induce or in return for purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any good, facility, item or service reimbursable, in whole or in part, under Medicare, Medicaid or other federal healthcare programs. The term "remuneration" has been broadly interpreted to include anything of value, including stock, stock options, and the compensation derived through ownership interests.

Recognizing that the federal Anti-Kickback Statute is broad and may prohibit many innocuous or beneficial arrangements within the healthcare industry, the United State Department of Health and Human Services ("DHHS") issued regulations in July 1991, which DHHS has referred to as "safe harbors." These safe harbor regulations set forth certain provisions which, if met in form and substance, will assure medical device manufacturers, healthcare providers and other parties that they will not be prosecuted under the federal Anti-Kickback Statute. Additional safe harbor provisions providing similar protections have been published intermittently since 1991. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Our arrangements with physicians, hospitals and other persons or entities who are in a position to refer may not fully meet the stringent criteria specified in the various safe harbors. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not fall within an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct *per se* illegal under the federal Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all its facts and circumstances. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the federal Anti-Kickback Statute has been violated. In addition, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Moreover, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act (described below).

Violations of the federal Anti-Kickback Statute may result in civil monetary penalties up to $100,000 for each violation, plus up to three times the remuneration involved. Civil penalties for such conduct can further be assessed under the federal False Claims Act. Violations can also result in criminal penalties, including criminal fines of up to $100,000 and imprisonment of up to 10 years. Similarly, violations can result in exclusion from participation in government healthcare programs, including Medicare and Medicaid. Liability under the federal Anti-Kickback Statute may also arise because of the intentions or actions of the parties with whom we do business. While we are not aware of any such intentions or actions, we have only limited knowledge regarding the intentions or actions underlying those arrangements. Conduct and business arrangements that do not fully satisfy one of these safe harbor provisions may result in increased scrutiny by government enforcement authorities. The majority of states also have anti-kickback laws which establish similar prohibitions and, in some cases, may apply more broadly to items or services covered by any third-party payor, including commercial insurers and self-pay patients.

The federal civil False Claims Act prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment or approval to the federal government or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. A claim includes "any request or demand" for money or property presented to the U.S. government. The federal civil False Claims Act also applies to false submissions that cause the government to be paid less than the amount to which it is entitled, such as a rebate. Intent to deceive is not required to establish liability under the civil federal civil False Claims Act.

In addition, private parties may initiate "qui tam" whistleblower lawsuits against any person or entity under the federal civil False Claims Act in the name of the government and share in the proceeds of the lawsuit. Penalties for federal civil False Claim Act violations include fines for each false claim, plus up to three times the amount of damages sustained by the federal government and, most critically, may provide the basis for exclusion from government healthcare programs, including Medicare and Medicaid. On May 20, 2009, the Fraud Enforcement Recovery Act of 2009, or FERA, was enacted, which modifies and clarifies certain provisions of the federal civil False Claims Act. In part, the FERA amends the federal civil False Claims Act such that penalties may now apply to any person, including an organization that does not contract directly with the government, who knowingly makes, uses or causes to be made or used, a false record or statement material to a false or fraudulent claim paid in part by the federal government. The government may further prosecute conduct constituting a false claim under the federal criminal False Claims Act. The criminal False Claims Act prohibits the making or presenting of a claim to the government knowing such claim to be false, fictitious or fraudulent and, unlike the federal civil False Claims Act, requires proof of intent to submit a false claim. When an entity is determined to have violated the federal civil False Claims Act, the government may impose civil fines and penalties ranging from $11,181 to $22,363 for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs.

The Civil Monetary Penalty Act of 1981 imposes penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal healthcare program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent, or offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary's decision to order or receive items or services reimbursable by the government from a particular provider or supplier.

HIPAA also created additional federal criminal statutes that prohibit among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

Many foreign countries have similar laws relating to healthcare fraud and abuse. Foreign laws and regulations may vary greatly from country to country. For example, the advertising and promotion of our products is subject to EU Directives concerning misleading and comparative advertising and unfair commercial practices, as well as other EEA Member State legislation governing the advertising and promotion of medical devices. These laws may limit or restrict the advertising and promotion of our products to the general public and may impose limitations on our promotional activities with healthcare professionals. Also, many U.S. states have similar fraud and abuse statutes or regulations that may be broader in scope and may apply regardless of payor, in addition to items and services reimbursed under Medicaid and other state programs.

Additionally, there has been a recent trend of increased foreign, federal, and state regulation of payments and transfers of value provided to healthcare professionals or entities. The federal Physician Payments Sunshine Act imposes annual reporting requirements on certain drug, biologics, medical supplies and device manufacturers for which payment is available under Medicare, Medicaid or Children's Health Insurance Program ("CHIP"), for payments and other transfers of value provided by them, directly or indirectly, to physicians (including physician family members), certain other healthcare providers, and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. A manufacturer's failure to submit timely, accurately and completely the required information for all payments, transfers of value or ownership or investment interests may result in civil monetary penalties ranging from $1,000 to $10,000 for each payment or other transfer of value that Is not reported (up to a maximum per annual report of $150,000) and from $10,000 to $100,000 for each knowing failure to report (up to a maximum per annual report of $1,150,000). Manufacturers must submit reports by the 90th day of each calendar year. Certain foreign countries and U.S. states also mandate implementation of commercial compliance programs, impose restrictions on device manufacturer marketing practices and require tracking and reporting of gifts, compensation and other remuneration to healthcare professionals and entities. Additionally, there are criminal penalties if an entity intentionally makes false statement in such reports. With some exceptions, the information that manufacturers report is made publicly available.

Data Privacy and Security Laws

We are also subject to various federal, state and foreign laws that protect the confidentiality of certain patient health information, including patient medical records, and restrict the use and disclosure of patient health information by healthcare providers, such as HIPAA, as amended by HITECH, in the United States.

HIPAA established uniform standards governing the conduct of certain electronic healthcare transactions and requires certain entities, called covered entities, to comply with standards that include the privacy and security of protected health information, or PHI. HIPAA also requires business associates, such as independent contractors or agents of covered entities that have access to PHI in connection with providing a service to or on behalf of a covered entity, of covered entities to enter into business associate agreements with the covered entity and to safeguard the covered entity's PHI against improper use and disclosure.

The HIPAA privacy regulations cover the use and disclosure of protected health information by covered entities as well as business associates, which are defined to include subcontractors that create, receive, maintain, or transmit protected health information on behalf of a business associate. They also set forth certain rights that an individual has with respect to his or her protected health information maintained by a covered entity, including the right to access or amend certain records containing protected health information, or to request restrictions on the use or disclosure of protected health information. The security regulations establish requirements for safeguarding the confidentiality, integrity, and availability of protected health information that is electronically transmitted or electronically stored. HITECH, among other things, established certain health information security breach notification requirements. A covered entity must notify any individual whose protected health information is breached according to the specifications set forth in the breach notification rule. The HIPAA privacy and security regulations establish a uniform federal "floor" and do not supersede state laws that are more stringent or provide individuals with greater rights with respect to the privacy or security of, and access to, their records containing protected health information or insofar as such state laws apply to personal information that is broader in scope than protected health information as defined under HIPAA.

HIPAA requires the notification of patients, and other compliance actions, in the event of a breach of unsecured protected health information, or PHI. If notification to patients of a breach is required, such notification must be provided without unreasonable delay and in no event later than 60 calendar days after discovery of the breach. In addition, if the PHI of 500 or more individuals is improperly used or disclosed, we would be required to report the improper use or disclosure to DHHS, Office of Civil Rights, which would post the violation on its website, and to the media. Failure to comply with the HIPAA privacy and security standards can result in civil monetary penalties up to $59,522 per violation, not to exceed $1,785,651 per calendar year for non-compliance of an identical provision, and, in certain circumstances, criminal penalties with fines up to $250,000 per violation and/or imprisonment.

HIPAA authorizes state attorneys general to file suit on behalf of their residents for violations. Courts are able to award damages, costs and attorneys' fees related to violations of HIPAA in such cases. While HIPAA does not create a private right of action allowing individuals to file suit against us in civil court for violations of HIPAA, its standards have been used as the basis for duty of care cases in state civil suits such as those for negligence or recklessness in the misuse or breach of PHI. In addition, HIPAA mandates that the Secretary of DHHS conduct periodic compliance audits of HIPAA covered entities, such as us, and their business associates for compliance with the HIPAA privacy and security standards. It also tasks DHHS with establishing a methodology whereby harmed individuals who were the victims of breaches of unsecured PHI may receive a percentage of the civil monetary penalty paid by the violator.

In the European Union, we may be subject to laws relating to our collection, control, processing and other use of personal data (i.e., data relating to an identifiable living individual). We process personal data in relation to our operations. We process data of both our employees and our customers, including health and medical information. The data privacy regime in the EU includes the EU Data Protection Directive (95/46/EC) regarding the processing of personal data and the free movement of such data, the E-Privacy Directive 2002/58/EC and national laws implementing each of them. Each EU Member State has transposed the requirements laid down by the Data Protection Directive and E-Privacy Directive into its own national data privacy regime and therefore the laws may differ by jurisdiction, sometimes significantly. We need to ensure compliance with the rules in each jurisdiction where we are established or are otherwise subject to local privacy laws.

The requirements include that personal data may only be collected for specified, explicit and legitimate purposes based on legal grounds set out in the local laws and may only be processed in a manner consistent with those purposes. Personal data must also be adequate, relevant, not excessive in relation to the purposes for which it is collected, be secure, not be transferred outside of the EEA unless certain steps are taken to ensure an adequate level of protection and must not be kept for longer than necessary for the purposes of collection. To the extent that we process, control or otherwise use sensitive data relating to living individuals (for example, patients' health or medical information), more stringent rules apply, limiting the circumstances and the manner in which we are legally permitted to process that data and transfer that data outside of the EEA. In particular, in order to process such data, explicit consent to the processing (including any transfer) is usually required from the data subject (being the person to whom the personal data relates).

The new EU-wide General Data Protection Regulation, or GDPR, became applicable on May 25, 2018, replacing the current data protection laws issued by each EU member state based on the Directive 95/46/EC. Unlike the Directive (which needed to be transposed at national level), the GDPR text is directly applicable in each EU member state, resulting in a more uniform application of data privacy laws across the EU. The GDPR imposes onerous accountability obligations requiring data controllers and processors to maintain a record of their data processing and policies. It requires data controllers to be transparent and disclose to data subjects (in a concise, intelligible and easily accessible form) how their personal information is to be used, imposes limitations on retention of information, increases requirements pertaining to pseudonymized (i.e., key-coded) data, introduces mandatory data breach notification requirements and sets higher standards for data controllers to demonstrate that they have obtained valid consent for certain data processing activities. Fines for non-compliance with the GDPR are significant—the greater of EUR 20 million or 4% of global turnover. The GDPR provides that EU member states may introduce further conditions, including limitations, to the processing of genetic, biometric or health data, which could limit our ability to collect, use and share personal data, or could cause our compliance costs to increase, ultimately having an adverse impact on our business.

We are subject to the supervision of local data protection authorities in those jurisdictions where we are established or otherwise subject to applicable law.

We depend on a number of third parties in relation to our provision of our services, a number of which process personal data on our behalf. With each such provider we enter into contractual arrangements to ensure that they only process personal data according to our instructions, and that they have sufficient technical and organizational security measures in place. Where we transfer personal data outside the EEA, we do so in compliance with the relevant data export requirements. We take our data protection obligations seriously, as any improper disclosure, particularly with regard to our customers' sensitive personal data, could negatively impact our business and/or our reputation.

Healthcare Reform

Economic, political and regulatory influences are continuously causing fundamental changes in the healthcare industry in the United States. In 2010, the U.S. Congress enacted and President Obama signed into law, significant reforms to the U.S. healthcare system. These reforms, contained primarily in the Patient Protection and Affordable Care Act of 2010 (the "PPACA") and its companion act, the Health Care Education and Reconciliation Act of 2010 (collectively, the "Health Reform Laws"), significantly altered the U.S. healthcare system by authorizing, among many other things: (i) increased access to health insurance benefits for the uninsured and underinsured populations; (ii) new facilitators and providers of health insurance, as well as new health insurance purchasing access points (i.e., exchanges); (iii) incentives for certain employer groups to purchase health insurance for their employees; (iv) opportunities for subsidies to certain qualifying individuals to help defray the cost of premiums and other out-of-pocket costs associated with the purchase of health insurance, and over the longer term; and (v) mechanisms to foster alternative payment and reimbursement methodologies focused on outcomes, quality and care coordination. In addition, certain states in which we operate are periodically considering various healthcare reform proposals.

Since their passage in 2010, the Health Reform Laws have triggered many changes to the U.S. healthcare system, some of which took effect (e.g., the subsequently eliminated individual mandate penalty) while others have continued to be delayed and subsequently repealed (e.g., the medical device tax). The Health Reform Laws also have faced several challenges and remain subject to ongoing efforts to repeal or modify the laws. For example, President Trump issued an Executive Order 13765 (Minimizing the Economic Burden of the Patient Protection and Affordable Care Act Pending Repeal) on January 20, 2017 granting authority to certain executive departments and agencies to minimize the economic burden of the PPACA. However, President Biden revoked this Executive Order on January 28, 2021 (as part of President Biden's Executive Order on Strengthening Medicaid and the Affordable Care Act) and directed heads of departments to "consider whether to suspend, revise, or rescind — and, as applicable, publish for notice and comment proposed rules suspending, revising, or rescinding" actions taken by the Trump Administration which may hinder the operation of the Health Reform Laws.

Nevertheless, the core tenets of the Health Reform Laws remain in effect with several exceptions. The individual mandate penalty was eliminated beginning in 2019 through the Tax Cuts and Jobs Act of 2017. In addition, on December 20, 2019, the Further Consolidated Appropriations Act, 2020 was signed into law which repealed several provisions that were included in the Health Reform Laws to pay for the increased federal spending associated with the Health Reform Laws. Specifically, Congress: (i) repealed the Medical Device Excise Tax, which imposed a 2.3% excise tax on manufacturers, producers and importers of certain medical devices; (ii) repealed the health insurance tax, which applies to most fully insured plans, beginning in 2021; and (iii) repealed the so-called Cadillac Tax, which imposed an excise tax of 40% on premiums for employer-sponsored individuals and families that exceeded a certain minimum threshold. Prior to these changes Congress had passed a short-term spending bill as part of the Continuing Appropriations Act of 2018 that delayed the implementation of these provisions and eliminated the Independent Payment Advisory Board, which was a 15-member panel of healthcare experts created by the Health Reform Laws and tasked with making annual cost-cutting recommendations for Medicare if Medicare spending exceeded a specified growth rate.

The Health Reform Laws have also been the subject of litigation. In particular, in 2019, a collection of 20 state governors and state attorneys general (subsequently two states have dropped out) filed a lawsuit against the federal government in the Northern District of Texas seeking to enjoin the entire Health Reform Laws following the elimination of the individual mandate penalty. The District Court ruled that without the penalty the individual mandate was unconstitutional and further held that all other provisions of the Health Reform Laws should be overturned as well. The U.S. Court of Appeals for the 5th Circuit affirmed the trial court's decision; however, instead of deciding whether the rest of the PPACA must be struck down, the 5th Circuit sent the case back to the trial court for additional analysis. In March of 2020 the United States Supreme Court agreed to review the case and heard oral arguments on November 10, 2020. On June 17, 2021, the Supreme Court held that the plaintiffs lacked standing and reversed the Fifth Circuit's judgment in respect to standing, vacated the Fifth Circuit's judgment, and remanded the case with instructions to dismiss the case. Subsequently the Fifth Circuit vacated the judgement of the District Court in its entirety and remanded the case to the District Court with instructions to dismiss. The District Court finally dismissed the case on July 27, 2021.

The Trump Administration made a number of changes that have affected the individual and small group exchange markets, including modifications to the open enrollment periods, funding cuts to patient support resources, including the patient navigator program, and failing to issue cost-sharing reduction payments to insurers participating in the exchanges. In June 2018, the Trump Administration published a final rule that allows small businesses and self-employed individuals to band together to create associations that are considered "employers" under the Employee Retirement Income Security Act ("ERISA") such that these associations are eligible to access large group health plans, which are typically less expensive and are not subject to as many of the consumer protections imposed by the PPACA on small group and individual health plans. In addition, the Trump Administration published a final rule which makes short term, limited duration plans more accessible, providing individuals with another product offering that is generally less expensive but has fewer protections than under the PPACA plans. This final rule combined with the association health plan final rule, may increase instability in the healthcare exchanges by siphoning off potentially healthier people from the risk pool. However, in 2021 President Biden issued an Executive Order on Strengthening Medicaid and the Affordable Care Act, directing heads of departments to review and potentially revoke or revise these Trump-era actions. In light of the ongoing efforts to alter the Health Reform Laws, we are unable at this time to predict the full impact that potential changes will have on our business, including provisions in the Health Reform Laws related to Medicare payments, mechanisms to foster alternative payment and reimbursement methodologies focused on outcomes, quality and care coordination, Medicare enrollment and claims submission requirements and revisions to other federal healthcare laws such as the federal Anti-Kickback Statute, the Stark Law and the federal False Claims Act.

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.

Human Capital Resources

As of December 31, 2021, we had 158 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, nine are part of finance and accounting, 11 are involved in senior management, 19 in sales and marketing, one in research, development and regulatory and 118 in 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 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 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 for additional ways to diversify our 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 have required personal protective equipment for patient-facing employees in addition to requiring daily health questionnaires and temperature checks. Many employees work remotely 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 933,334 shares of common stock to a group of our founders, including Summit Capital USA (now Upeva, Inc., 666,667 shares), Regal Capital Venture Partners LLC (166,667 shares) and Thomas P. Madden (100,000 shares) at a purchase price of $0.0003 per share (for an aggregate of $280 of proceeds).

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 protocols 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.

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 333,334 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 833,333 share of common stock such that, after amendment and restatement of the 2019 Plan, 1,166,667 shares of common stock will be available for issuance under the 2019 Plan. The 2019 Plan permits grants of equity awards to employees, directors, consultants and other independent contractors.

Approval of Transfer of Corporate Domicile and Reverse Stock Split

On April 18, 2019, our stockholders voted to authorize our board of 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 of directors to transfer our corporate domicile from Wyoming to another U.S. state. Our board of 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 of 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 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.

Corporate Information

Our principal offices are located at 9137 Ridgeline Boulevard, Suite 135, Highlands Ranch, Colorado 80129, and our telephone number is (866) 908-4867. Our website is *www.vivos.com* and the information that can be accessed through our website is not part of this Annual Report on Form 10-K.

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.

Our business was formed only in 2016, and therefore you have 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, you have 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. For the fiscal years ended December 31, 2021 and 2020, we reported net losses of $20.3 million and $12.1 million respectively, and negative cash flow from operating activities of $15.7 million and $5.7 million, respectively. As of December 31, 2021, we had an aggregate accumulated deficit of $55.6 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.

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 limited experience 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 this new business model that we are unable to presently identify, such as pricing, competition, marketing and regulatory risks. 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.

We will need to raise additional capital 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 to fund and grow our business, 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. 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.

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.

We have identified a material weakness in our internal control over financial reporting.

Prior to our initial public offering in December 2020, we were a private company and had limited accounting and financial reporting personnel and other resources with which to address our internal controls and related procedures. In connection with the audit of our consolidated financial statements for the years ended December 31, 2021 and 2020, we and our independent registered public accounting firm identified a material weakness in our internal control over financial reporting (see Item 9A of this report for further information). A material weakness is a deficiency, or a combination of deficiencies, 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 material weakness in our case 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 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*. 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 conclude that our internal control over financial reporting is not effective, which could adversely impact our investors' confidence and our stock price.

We expect to derive a substantial portion of our prospective future revenue from sales of our appliances and protocols, 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. Our secondary source of revenue is our clinical training and practice support programs, including Billing Intelligence Services, Airway Intelligence System and AireO^2. We expect that sales of the component aspects of The Vivos Method and our services to our VIPs related to the use of such protocols 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 a in very few select countries such as South Korea, Australia, Japan and India. The Vivos Method is different from current surgical and non-surgical treatments dentofacial abnormalities and/or mild to moderate 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 protocol and decreased or lower than expected sales or recruitment and maintenance of new VIPs would cause us to lose all or substantially all of our revenue.

We will not be successful if The Vivos Method is not sufficiently adopted by the medical and dental communities, including independent practitioners and dental service organizations (DSOs) for the treatment of dentofacial abnormalities and/or mild to moderate OSA and snoring.

We believe that The Vivos Method is the first commercially available protocol based on our proprietary technology for the treatment of dentofacial abnormalities and/or mild to moderate 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 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 OSA and referring physicians must write a prescription for the use of a Class II Vivos appliance;

- 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 OSA using The Vivos Method.

In reference to the treatment of mild to moderate 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 protocols 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 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 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) 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 recurrences of COVID-19), thus negatively impacting our product revenues. 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.

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.

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.

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;
- 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.

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 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 OSA and snoring by both physicians/dentists 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, 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;
- 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 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;
- seasonal fluctuations in revenue due to the elective nature of sleep-disordered breathing treatments for mild to moderate 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 is a new business offering for us, and it 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 to make the program a successful revenue generator for us.

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 The Vivos Method may adversely impact our ability to generate revenue if they do not demonstrate that The Vivos Method is clinically effective for currently specified or expanded indications or if they are not completed in a timely manner.

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 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.

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 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 OSA.

The cost of treatments for dentofacial abnormalities and/or mild to moderate 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 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.

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.

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;
- 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 pulmonologists, 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 by their primary care physicians. Pulmonologists 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 pulmonologist, the pulmonologist typically prescribes CPAP as the therapy of choice. Although we offer The Vivos Method through our VIPs, our domestic sales organization does not generally call on pulmonologists or third-party sleep centers to sell The Vivos Method, and we do not believe that most pulmonologists today would recommend The Vivos Method to their patients with mild to moderate OSA. We cannot predict the extent to which pulmonologists 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.

We face significant competition in the rapidly changing market for mild to moderate OSA and snoring in adults, and we may be unable to manage competitive pressures.

The market for treating mild to moderate 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 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 disordered breathing 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.

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 protocols 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;
- 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.

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.

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 protocols. 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, protocols and any future products are covered by valid and enforceable patents or are effectively maintained as trade secrets.

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.

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 protocols. 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 protocols. 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.

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.

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 a 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 a 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;
- 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.

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 protocols 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.

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 and Empower Sleep 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 OSA and snoring 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 protocols, 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.

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.

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. Our marketing activities are principally focused on increasing brand awareness in the communities in which we provide services. As we onboard VIP providers, we expect to undertake aggressive marketing campaigns to increase community awareness about our presence and our service capabilities. 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. If we are not successful in these efforts, we will have incurred expenses without materially increasing revenue.

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.

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 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 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 the 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.

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.

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.

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;
- 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, 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;
- 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
- 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 our appliances and associated protocols 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 protocols off label. Furthermore, the use of our appliances and associated protocols 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.

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, 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.

We may 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 may pursue acquisitions or licenses of technology to, among other things, expand the scope of products services we provide. 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.

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.

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 and our Chief Financial Officer, Brad Amman. 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 of 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 in 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.

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 of this key technology would seriously impair our business and future viability, and could result in delays in developing, introducing or maintaining our protocols/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.

Our failure to obtain government approvals, including required FDA approvals, or to comply with ongoing 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.

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. Each Class I and 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;
- 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;
- withdrawing a 510(k) clearance already granted; and
- criminal prosecution.

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. While we believe these issues have been resolved, to date the FDA has made no definitive statement that the matters raised by such letter have been satisfactorily resolved.

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. 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, for Colorado only, we may be regarded as a DSO. Nevertheless, if we were 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.

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.

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 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 may be highly volatile, and you could lose all or part of your investment.

The market price of our common stock has at times been, and is likely in the future to be, volatile. This 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.

Our failure to meet the continuing listing requirements of The Nasdaq Capital Market could result in a de-listing 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.

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. See "Certain Relationships and Related Party Transactions" for further information on the foregoing transactions with Dr. Singh.

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, in the aggregate, representing approximately 14% of our outstanding voting capital stock. In addition, Dr. Dave Singh, our former Chief Medical Officer and director, owns an additional 17.8% 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 significant 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.

In addition, this concentration of voting power was evidenced in April 2020, when Mr. Huntsman, Dr. Singh and a small group of additional shareholders acted to remove three independent members of our board of directors and appoint new members of our board of directors. These shareholders could continue to exert this voting power.

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 of 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 of 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 of 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 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;
- 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.

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 of 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 of 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 of 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.

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.

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.

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.

None.

Item 2. Properties

We lease approximately 5,472 rentable square feet of office space from an unaffiliated third party for our corporate office located at 9137 Ridgeline Boulevard, Suite 135 and Suite 280, Highlands Ranch, Colorado. This lease expires in May 2022 prior to which time we will renew or enter into a new lease. Terms of the office lease currently provide for a base rent payment of $8,436 per month. We also lease approximately 2,220 rentable square feet of space from an unaffiliated third party for one of our Vivos Centers located at 4795 Larimer Parkway, Johnstown, Colorado. This lease expires in February 2025. Terms of the office lease provide for a base rent payment of $3,608 per month and a share of the buildings operating expenses such as taxes and maintenance of $2,035 per month. We also lease 3,643 rentable square feet of space from an unaffiliated third party for our Vivos Center located at 9135 Ridgeline Boulevard, Highlands Ranch, Colorado. This lease expires in January 2029. Terms of the office provide for a base rent payment of $5,465 per month and a share of the building's operating expenses such as taxes and maintenance of $3,273 per month. Effective May 20, 2019, we entered into a lease at 7001 Tower Road, Denver, Colorado for 14,732 rentable square feet for the Vivos Institute and amended the lease effective March 11, 2022 to increase the premises by 9,129 rentable square feet for a total of 23,861 rentable square feet. This facility was built primarily as a training facility where our VIPs are trained and the additional square footage is for office space and fulfillment. We believe that these facilities are adequate for our current and near-term future needs.

Item 3. Legal Proceedings.

From time to time, we are involved in various claims and legal actions arising in the ordinary course of business.

On April 13, 2021, the Washington State Department of Financial Institutions ("WSDFI") sent a letter and subpoena requesting that we produce certain documents and records. WSDFI is investigating certain sales of our common stock by a previous employee and independent contractor in Washington prior to our initial public offering. This subject matter in general (including activities of such previous employee and independent contractor) had been among the issues previously investigated by a joint committee of our board of directors and internal and external legal counsel that commenced in February 2020 and, pursuant to the findings and recommendations of the joint committee, led to the company implementing in April 2020 certain enhanced corporate governance policies (in the form of a formal written policy on private stock sales requiring prior approval of our internal or external legal counsel and changes to certain organizational matters). We have cooperated with WSDFI regarding this investigation, but during and subsequent to the year ended December 31, 2021, we have not been made aware of any developments with the investigation.

On June 5, 2020, we filed suit against Ortho-Tain, Inc.("Ortho-Tain") in the United States District Court for the District of Colorado seeking relief from certain false, threatening, and defamatory statements to our business affiliate, Benco Dental ("Benco"). We believe such statements have interfered with our business relationship and contract, causing harm to our reputation, loss of goodwill, and unspecified monetary damages. On February 12, 2021, we amended our complaint to add claims for false advertising and unfair business practices, as well as additional variants of the original claims to address Ortho-Tain's alleged false advertising campaign against us in the fall of 2020. Our amended complaint seeks permanent injunctive relief to prevent what we believe are defamatory statements and interference with our business relationships by Ortho-Tain. We further seek declaratory relief to refute the defendant's false allegations, as well as monetary damages. Prior to filing suit, we worked collaboratively with legal counsel at Benco to address and resolve this matter. Such efforts were unsuccessful. On February 26, 2021, Ortho-Tain, Inc. filed a motion to dismiss the amended complaint. We opposed the motion. On September 3, 2021, the District Court denied the motion to dismiss on all grounds and lifted the stay of discovery. On September 7, 2021, Ortho-Tain filed a notice of appeal of the District Court's order to the United States Court of Appeals for the Tenth Circuit. On September 21, 2021, we filed a motion to dismiss the appeal for lack of jurisdiction. On October 12, 2021, the Court of Appeals referred the motion to dismiss the appeal to the merits panel for decision along with the merits. The appeal is now fully briefed and awaiting decision form the Tenth Circuit.

On July 22, 2020 Ortho-Tain, Inc. filed a complaint in the United States District Court for the Northern District of Illinois naming our company, along with our Chairman and Chief Executive Officer, R. Kirk Huntsman, Benco Dental Supply Co., Dr. Brian Kraft, Dr. Ben Miraglia, and Dr. Mark Musso (the "Illinois Ortho-Tain Case"). The complaint in the Illinois Ortho-Tain Case addresses the same events as the suit we filed against Ortho-Tain, Inc. in June 2020 as described above. The complaint in the Illinois Ortho-Tain Case alleges violation of the Lanham Act and an alleged civil conspiracy among the defendants to violate the Lanham Act by an alleged false designation of origin related to a presentation given by Dr. Brian Kraft at an event sponsored by us and Benco Dental. Ortho-Tain also alleges that the actions of the defendants, including our company, diverted sales from Ortho-Tain, deprived Ortho-Tain of advertising value and resulted in a loss of goodwill to Ortho-Tain. Ortho-Tain also alleges two separate breach of contract actions against Dr. Brian Kraft and Mr. Huntsman. Ortho-Tain's allegation of breach of contract against Mr. Huntsman, relates to a Non-Disclosure Agreement entered into in October 2013 with Mr. Huntsman's prior entity, Xenith Practices, LLC, which Non-Disclosure Agreement expired pursuant to its terms in October 2016. We continue to evaluate the allegations, although we believe they lack merit and think Ortho-Tain will be unable to establish actionable damages. On September 9, 2020, we moved to dismiss the claims against us in the Illinois Ortho-Tain Case. On October 23, 2020, we filed a motion requesting, in the alternative, that if the case is not dismissed, it be transferred to the Colorado action described above or stayed. On May 14, 2021, the Court granted our motion to stay the Illinois Ortho-Tain Case, pending resolution of the Colorado action described above. On September 3, 2021 and again on December 2, 2021., the Court extended the stay. The case remains stayed.

On May 17, 2021, plaintiff Steven Rospond ("Rospond") filed a lawsuit against Proceed Finance asserting claims for breach of contract and violation of the Kansas Consumer Protection Act against Defendants Proceed Finance and Security First Bank regarding a $50,000 loan Rospond took to pay for services provided by our company. Rospond sent us a subpoena seeking various documents relating to the services provided by us to which it responded and provided documents on December 21, 2021. In an Order dated October 26, 2021, the court granted Rospond an extension of up to seven days after we delivered documents to Rospond within which to amend his lawsuit, including to assert claims against us. To date, we have no knowledge of Rospond asserting any claims against us. According to the court's docket, this lawsuit is still pending and has not been dismissed.

There are no other legal proceedings currently pending against us, or known to be contemplated by any governmental agency, which we believe would have a material effect on our business, financial position or results of operations.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our common stock began trading on Nasdaq under the symbol "VVOS" on December 11, 2020. Prior to that date, there was no established public trading market for our common stock.

Holders

As of March 23, 2022, there were approximately 5,400 holders of record of our common stock. This number does not include stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Recent Sales of Unregistered Securities

None.

Securities Authorized for Issuance under Equity Compensation Plans

The following table provides information as of December 31, 2021, regarding our common stock that may be issued under our 2017 stock and option award plan (the "2017 Plan"), and our 2019 stock and option award plan (the "2019 Plan").

	Shares to be Issued Upon Exercise of Outstanding Options, and Rights		Securities Available
Plan Category:	**Number of Shares**	**Weighted Average Exercise Price**	**For Future Issuance**
Equity compensation plans approved by security holders:			
2017 Plan	1,333,333[1]	$ 4.97	-
2019 Plan	1,018,000[2]	7.27	1,098,667
Equity compensation plans not approved by stockholders:	500,001[3]	1.60	-
Total	2,851,334	5.23	1,098,667

(1) The 2017 Plan permits grants of equity awards to employees, directors, consultants and other independent contractors. Our board of directors and shareholders have approved a total reserve of 1,333,333 shares for issuance under the 2017 Plan.

(2) The 2019 Plan permits grants of equity awards to employees, directors, consultants and other independent contractors. Our board of directors and shareholders have approved a total reserve of 2,366,667 shares for issuance out of which 250,000 shares have been exercised under the 2019 Plan.

(3) Represents options granted to officers and employees prior to the approval by our stockholders of the 2017 Plan.

Dividend Policy

As of the date of this Annual Report on Form 10-K, we have not paid any cash dividends to stockholders. The declaration of any future cash dividend will be at the discretion of our board of directors and will depend upon our earnings, if any, our capital requirements and financial position, the general economic conditions, and other pertinent conditions. It is our present intention not to pay any cash dividends in the foreseeable future, but rather to reinvest earnings, if any, in our business operations.

Item 6. Reserved.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our financial statements and the related notes to those statements included elsewhere in this Annual Report on Form 10-K. In addition to historical financial information, the following discussion and analysis contains forward-looking statements that involve risks, uncertainties, and assumptions. Some of the numbers included herein have been rounded for the convenience of presentation. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of many factors, including those discussed under Part I. "Item 1A. Risk Factors'' and elsewhere in this Annual Report on Form 10-K.

Overview

We are a revenue stage medical technology company focused on the development and commercialization of innovative treatment alternatives for patients with dentofacial abnormalities and/or patients diagnosed with mild to moderate obstructive sleep apnea (OSA) and snoring in adults. We believe our technologies and protocols represent a significant improvement in the treatment of mild to moderate OSA versus other treatments such as continuous positive airway pressure (or CPAP) or palliative oral appliance therapies. We call our alternative treatment protocol ***The Vivos Method***.

The Vivos Method is an advanced therapeutic protocol, which often combines the use of customized oral appliance specifications and proprietary clinical protocols developed by our company and prescribed by specially trained dentists in cooperation with their medical colleagues. Published studies have shown that using our customized appliances and clinical protocols led to significantly lower Apnea Hypopnea Index scores and improve other conditions associated with OSA. Our patented oral appliances have proven effective (within the scope of the U.S. Food and Drug Administration (or FDA) cleared uses) in approximately 25,000 patients treated worldwide by more than 1,450 trained dentists.

Our business model is focused around dentists, and our program to train independent dentists and offer them other value-added services in connection with their ordering and use of The Vivos Method for patients is called the Vivos Integrated Practice ("VIP") program.

On December 11, 2020, we completed our initial public offering by issuing 4,025,000 shares of our common stock, at a public offering price of $6.00 per share, for net proceeds of approximately $21.6 million after deducting underwriting discounts and commissions and offering expenses payable by us.

On May 11, 2021, we completed a follow-on underwritten public offering of 4,600,000 shares of our common stock at a price of $6.00 per share, for net proceeds of approximately $25.4 million after deducting underwriting discounts and commissions and offering expenses payable by us.

Impact of COVID-19

In December 2019, a novel strain of coronavirus known as COVID-19 was reported to have surfaced in China, and by March 2020 the spread of the virus resulted in a world-wide pandemic. By March 2020, the U.S. economy had been largely shut down by mass quarantines and government mandated stay-in-place orders (the "Orders") to halt the spread of the virus. Many of these Orders have been relaxed or lifted in jurisdictions where large portions of the population have been vaccinated, but there is considerable uncertainty about whether the Orders will need to be reinstated due to the ongoing spread of new variants of COVID-19. A significant portion of the worldwide population remains unvaccinated, and uncertainty also exists about whether existing vaccines will be effective as new variants of COVID-19 emerge. Accordingly, the overall impact of COVID-19 continues to have an adverse impact on global business activities.

Many of our VIPs and potential VIPs closed their offices during 2020 as a result of COVID-19, although some remained open to specifically provide patients our products as our appliances and VIPs were deemed an essential business for health considerations in many jurisdictions. In the face of the pandemic and the results potential for revenue reduction, we worked diligently to reduce expenses and maintain revenues during 2020. While revenue growth flattened in March and April 2020, expenses were reduced and we aggressively expanded our network of healthcare providers familiar with our products by offering online continuing education courses which introduced many in the medical and dental communities to our product line. As businesses continued to reopen through 2021, the impact of COVID-19 on our company began to diminish, although we continue to closely monitor the potential impact of COVID-19 variants on our business. Of note, during the second half of 2021, many of our Canadian VIPs have not traveled to the U.S. for training in light of travel restrictions. As of August 9, 2021, the Government of Canada imposed further restrictions on unvaccinated travelers, which has caused delays with some of our Canadian VIPs receiving required training and commencing Vivos Method cases.

In addition, our fourth quarter 2021 revenue growth was impacted by lower VIP enrollments due largely to the COVID-19 Omicron variant resurgence. We achieved sales growth despite seeing significant headwinds throughout our core customer base, mostly driven by COVID-19 Delta and Omicron variant resurgences in the middle and latter part of the year. In December 2021, the American Dental Association reported that just 60% of dental practices were open and operating with business as usual. Another industry source reported 92% of dental practices were struggling to hire or replace hygienists, and 77% reported difficulty hiring front desk positions. These challenges across the dental community have impacted both VIP enrollments and patient case starts, as replacement dental personnel must be trained in the proper use of The Vivos Method. The world-wide response to the pandemic resulted in a significant downturn in economic activity, which we believe has continued to some degree into 2022 as a new variant (called B.A.2) has emerged. There is no assurance that government stimulus programs will successfully restore the economy to the levels that existed before the pandemic and there is a risk that new variant outbreaks will cause additional disruptions and slowdowns in the economy.

In addition, worldwide supply chain constraints and inflation, as well as Russia's invasion of Ukraine in February 2022, have emerged as new barriers to long-term economic recovery. If an economic recession or depression commences and is sustained, it could have a material adverse effect on our business as demand for our products could decrease.

As such, the long-term financial impact on our business of COVID-19 as well as these other matters cannot reasonably be fully estimated at this time.

Recent Developments

In January 2022, we announced the filing of a U.S. patent application related to certain new and enhanced clinical methods and proprietary protocols developed within The Vivos Method treatment for dentofacial abnormalities and/or OSA. This new patent application was based on early field data which revealed an additional 58% average improvement in AHI score reductions in OSA patients who had received treatment with The Vivos Method where the revised clinical protocols were implemented.

In December 2021, we announced that we received acceptance from a Centers for Medicare & Medicaid Services Pricing, Data Analysis and Coding (or PDAC) contractor for our mmRNA device for treating mild to moderate OSA and snoring in adults. This acceptance places the mmRNA device on the PDAC list of oral appliances covered by and billable to Medicare. This development makes benefits of the mmRNA device available to millions of Medicare beneficiaries who seek effective treatment for mild to moderate OSA.

Also in December 2021**,** we announced our official registration with Health Canada, the Ministry of Health department responsible for helping Canadians maintain and improve their health through services and resources. The official registration of our products will aim to provide patients with a comprehensive, end-to-end solution for OSA patients, which incorporates clinical screening, medical diagnosis and therapy using Vivos products. At the core of this development, we will offer our comprehensive line of highly effective oral appliances and proprietary clinical protocols to approximately 25,000 dentists across Canada who have millions of patients in search of an alternative treatment for dentofacial abnormalities and/or mild to moderate OSA and snoring.

Material Items and Trends Impacting Our Business

We believe that the following items and trends may be useful in better understanding our results of operations.

New VIP Enrollments (Service Revenue). Enrolling denta1 practices as VIPs is the first step in our ability to generate new revenue. As part of the VIP enrollment fee, we enter into a service contract with VIPs under which they receive training on the use of the Vivos treatment protocol. VIPs have the ability to start generating revenue for us and themselves after this training. To entice dentists to enroll as VIPs, we have worked with different marketing programs (which we generally call a "discovery track") with respect to the payment of VIPs enrollment fee, including discounts and payment plans. Once VIPs execute their VIP enrollment agreement, the discovery track allows the VIP 45 to 60 days to obtain financing and pay the enrollment fee. In general, however, we recognize 50% of the service revenue associated with enrollment fees in the second month of enrollment and the remaining 50% pro rata throughout the following eleven months of the enrollment service contract. Ongoing support and additional training is provided throughout the year under the services contract, which includes access to our proprietary Airway Intelligence Services, which provides the VIP with resources to help simplify the sleep apnea diagnostic and Vivos treatment planning process.

In addition to enrollment service revenue, we offer additional services, such as our Billing Intelligence Services offering, and MyoCorrect orofacial myofunctional therapy services, which was introduced in April 2021. Revenue for these services is recognized monthly during the month the services are rendered.

We are also engaging in strategic collaborations to market the benefits of the Vivos treatment protocol and VIP enrollment to dentists, including our August 2021 cooperative relationship with Empower Sleep to provide diagnostic and medical consultation services to people across North America who suffer from OSA and our October 2021 cross marketing collaboration with Candid Care, the maker of the *CandidPro* clear aligner for straightening teeth.

As the VIP program has matured, we have noted that approximately forty percent (40%) of dentists on average during 2021 (almost exclusively on a VIP discovery track) who enroll as VIPs later decide to cancel participation in the VIP program (although the percentage has varied from quarter to quarter). In order to properly reflect this occurrence in the discussion of our results of operations below, for the period ended December 31, 2021 we have shown new VIP enrollments for the period on a "net of cancellations" basis.

New VIP Case Starts (Product Revenue). Enrolling new VIPs is key to our ability to generate revenue, but equally as important is the number of Vivos treatment case starts that our VIPs commence, as these lead to appliance orders and related revenue. Once a VIP is fully trained, we encourage them to start cases. However, our experience has been that VIPs typically start slowly as they introduce The Vivos Method into their practices. While we work with VIPs to screen their patients for OSA with our SleepImage home sleep apnea ring test (which we expect will encourage Vivos Method case starts), not all VIPs incorporate our The Vivos Method into their practices at the same rate. We utilize Practice Advisors to help VIPs with onboarding and starting and increasing case starts over time. We believe VIPs can recoup their investment in VIP enrollment with approximately eight Vivos Method case starts, but as noted above, many VIPs start and also maintain their case starts at a significantly slower rate. We presently have a concentration of active VIPs who regularly start new Vivos Method treatment cases, with approximately thirty percent (30%) of VIPs accounting for all new case starts during the quarter ended December 31, 2021. We are working not only to increase the number of VIPs overall, but the number of active VIPs in terms of case starts. More active VIPs are also more likely to take advantage of our other service revenue generating offerings such as MyoCorrect orofacial myofunctional therapy and medical Billing Intelligence Services.

Marketing to DSOs. During the second half of 2021, we increased our efforts to market The Vivos Method and related products and services to larger dental service organizations ("DSOs"). Marketing to DSOs creates an opportunity to enroll and onboard multiple dental practices as VIPs under one common ownership structure. This would allow us to leverage training and support across multiple VIP practices and gain economies of scale with the goal of faster growth, both in VIP enrollments and in Vivos case starts. Our other dentist enrollment program, which we refer to as the Airway Alliance Program ("AAP"), was also established in the fourth quarter of 2021 and launched in the first quarter of 2022. This program is designed to attract the vast majority of the estimated 200,000 U.S. and Canadian dentists who are being strongly encouraged by the American Dental Association to screen their patients for sleep apnea. The AAP gives these dentists the simple yet profitable way to screen their patients for mild to moderate OSA using the SleepImage HST. Patients with mild to moderate OSA can be referred to a fully trained local VIP dentist for treatment.

Inflation. We believe the U.S. has entered a period of inflation which has increased (and may continue to increase) our, and our suppliers' costs as well as the end cost of our products to consumers. To date, we have been able to manage inflation risk without a material adverse impact on our business or results of operations. However, we anticipate that inflationary pressures will make it necessary for us to adjust our standard pricing for our appliance products effective second quarter of 2022. The full impact of such price adjustments on sales or demand for our products is not fully known at this time and may require us to adjust other aspects of our business as we seek to grow revenue and, ultimately, achieve profitability and positive cash flow from operations.

Supply Chain. From time to time, we may experience supply chain challenges due to forces beyond our control. For example, the Suez Canal blockage earlier in 2021 caused some delay in shipments of SleepImage rings from China. Overall, however, as our appliances are made in the U.S., we have not experienced significant supply chain issues as a result of COVID-19 or otherwise, although this may change in future periods.

*Seasonality***.** 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.

Cybersecurity. We have established procedures to escalate enterprise level issues, including cybersecurity matters, to the appropriate management levels within our organization and our board of directors, or members or committees thereof, as appropriate. Under our framework, cybersecurity issues, including those involving vulnerabilities introduced by our use of third-party software, are analyzed by subject matter experts for potential financial, operational, and reputational risks, based on, among other factors, the nature of the matter and breadth of impact. Matters determined to present potential material impacts to our financial results, operations, and/or reputation are immediately reported by management to the board of directors, or individual members of committees thereof, as appropriate, in accordance with our escalation framework. In addition, we have established procedures to ensure that members of management responsible for overseeing the effectiveness of disclosure controls are informed in a timely manner of known cybersecurity risks and incidents that may materially impact our operations and that timely public disclosure is made, as appropriate.

Key Components of Consolidated Statements of Operations

Net revenue. We recognize revenue when we satisfy our performance obligations over time as our customer receive the benefit of training and/or we transfer control of the promised products to our customers, which generally occurs over a very short period of time. Performance obligations are typically satisfied by shipping or delivering products to customers, or customers receiving training, which is also the point when title transfers and/or training occurs. Revenue consists of the gross sales price, net of estimated allowances, discounts, and personal rebates that are accounted for as a reduction from the gross sale price.

Cost of sales. Cost of goods sold primarily consists of direct costs attributable to the purchase from third party suppliers and related products. It also includes freight costs, fulfillment, distribution, and warehousing costs related to products sold.

Sales and marketing. Sales and marketing costs primarily consist of personnel costs for employees engaged in sales and marketing activities, commissions, advertising and marketing costs, website enhancements, and conferences for our sales and marketing staff.

General and administrative expenses. General and administrative ("G&A") expenses consist primarily of personnel costs for our administrative, human resources, finance and accounting employees, and executives. General and administrative expenses also include contract labor and consulting costs, travel-related expenses, legal, auditing and other professional fees, rent and facilities costs, repairs and maintenance, and general corporate expenses.

Depreciation and amortization expense. Depreciation and amortization expense is comprised of depreciation expense related to property and equipment, amortization expense related to leasehold improvements, and amortization expense related to identifiable intangible assets.

Interest expense. Interest expense is incurred under our loan under the U.S. Small Business Administration's Payroll Protection Program (PPP). The components of interest expense include the amount of interest payable in cash at the stated interest rate, and accretion and amortization of debt discounts and issuance costs.

Interest income. Interest income relates to temporary cash investments and a note receivable from a related party arising from the sale of our former company-owned dental clinic in Orem, Utah in 2019. The components of interest income from the note receivable include interest at the stated rate and accretion of the debt discount. Due to the impairment of the note receivable, no interest will be accrued starting January 1, 2022.

Results of Operations

Comparison of Years ended December 31, 2021 and 2020

Our consolidated statements of operations for the years ended December 31, 2021 and 2020 are presented below (dollars in thousands):

	2021	2020	Change
Revenue			
Product revenue	$ 6,520	$ 4,890	$ 1,630
Service revenue	10,365	8,176	2,189
Total revenue	16,885	13,066	3,819
Cost of sales (exclusive of depreciation and amortization shown separately below)	4,281	2,653	1,628
Gross profit	12,604	10,413	2,191
Gross profit %	*75%*	*80%*	
Operating expenses			
General and administrative	25,791	16,090	9,701
Sales and marketing	5,551	2,314	3,237
Litigation settlement	-	3,331	(3,331)
Impairment loss	911	-	911
Depreciation and amortization	733	718	15
Operating loss	(20,382)	(12,040)	(8,342)
Non-operating income (expense)			
Interest expense	(14)	(96)	82
Other expense	(9)	-	(9)
Interest income	117	79	38
Net loss	$ (20,288)	$ (12,057)	$ (8,231)

Revenue

Revenue increased by $3.8 million, or 29%, to $16.9 million for the year ended December 31, 2021 compared to $13.1 million for the year ended December 31, 2020. This increase consists of (i) approximately $1.5 million attributable to higher appliance sales to VIPs to volume increases, (ii) an increase of approximately $1.0 million in VIP revenue, (iii) an increase of approximately $1.1 million in center revenue, initial management service revenue including our MID program, and from the introduction of our orofacial myofunctional therapy services, and (iv) an increase of approximately $0.3 million in BIS revenue. Revenue growth was impacted by the COVID-19 Delta and Omicron variant resurgences. We achieved sales growth despite seeing significant headwinds throughout our core customer base, mostly driven by COVID-19 Delta and Omicron variant resurgences in the middle and latter part of the year. In December 2021, the American Dental Association reported that just 60% of dental practices were open and operating with business as usual. Another industry source reported 92% of dental practices were struggling to hire or replace hygienists, and 77% reported difficulty hiring front desk positions. These challenges across the dental community have impacted both doctor enrollments and patient case starts, as replacement dental personnel must be trained in The Vivos Method.

During the year ended December 31, 2021, we enrolled 197 VIPs net of cancellations and recognized VIP revenue of approximately $8.5 million, an increase of 2% compared to the year ended December 31, 2020, when we enrolled 194 VIPs net of cancellations for a total of approximately $7.5 million. The 13% increase in total revenue was primarily driven by (i) higher enrollments that took place in June, August, and September of which 50% of the enrollment fees were recognized during the year ended December 31, 2021, (ii) revenue recognized from higher prior year enrollments, and (iii) a higher price per VIP enrollment 2021 of $40,000 per contract, when compared to $32,000 per VIP contract in 2020. VIP enrollment revenue is recognized 50% in the second month of enrollment and the remaining 50% pro rata throughout the following eleven months of the service contract.

For the year ended December 31, 2021, we sold 11,355 oral appliance arches for a total of approximately $6.0 million, a 33% increase from the year ended December 31, 2020 when we sold 8,135 total oral appliance arches for a total of approximately $4.5 million. Additionally, for the year ended December 31, 2021 we had approximately $0.9 million in BIS revenue, a 46% increase from the year ended December 31, 2020 with approximately $0.6 million in revenue. Lastly, for the year ended December 31, 2021 we had approximately $0.8 million in center revenue and management service revenue including our MID program, compared to approximately $0.4 million for the year ended December 31, 2020, and approximately $0.4 million in our orofacial myofunctional therapy revenue, compared to none for the year ended December 31, 2020 due to the introduction of these services in 2021, and approximately $0.3 million for SleepImage subscriptions, sponsorships, and seminar revenue for the year ended December 31, 2021, compared to $0.2 million for the year ended December 31, 2020.

Cost of Sales and Gross Profit

Cost of sales increased by approximately $1.6 million to approximately $4.3 million for the year ended December 31, 2021 compared to approximately $2.7 million for the year ended December 31, 2020. This increase was primarily due to product and services costs associated with higher sales volume of our appliances, additional costs associated with VIP enrollments, and billing and myofunctional therapy revenue. Cost of sales includes approximately $0.8 million increase related to the deployment of SleepImage rings as part of the VIP enrollment package, and approximately $0.1 million increase related to the leasing of SleepImage rings in 2021. Additionally, we had an increase of approximately $0.5 million related to costs associated with appliances and approximately $0.1 million related to costs associated with our orofacial myofunctional therapy revenue.

For the year ended December 31, 2021, gross profit increased by approximately $2.2 million to $12.6 million. This increase was attributable to an increase in total revenue of $3.8 million as discussed above, partially offset by an increase in cost of sales of $1.6 million. Gross margin decreased to 75% for the year ended December 31, 2021 compared to 80% for the year ended December 31, 2020, primarily driven by the higher costs associated with VIP enrollments.

General and Administrative Expenses

General and administrative expenses increased approximately $9.7 million, or approximately 60%, to approximately $25.7 million for the year ended December 31, 2021, as compared to $16.1 million for the year ended December 31, 2020. The primary driver of this increase was an increase in personnel and related compensation of approximately $4.6 million, including salaries, bonuses, paid time off, stock-based compensation, and other employee-related expenses. The increase in payroll related costs were mainly a result of increased headcount (from 93 employees at December 31, 2020 to 158 employees at December 31, 2021). Other drivers of the increase in general and administrative expenses included an increase of approximately $1.2 million to general corporate costs such as director and officer insurance premiums and professional fees, an increase of approximately $0.9 million for information and technology supplies and equipment, approximately $1.2 million increase of bad debt expense driven by the increase in sales, and approximately $0.8 million in other corporate expenses such as filing fees, subscriptions, and office expenses, and an increase of approximately $0.1 million for office rent and utilities. These increases were due to the growth of the company combined with higher headcount and expenses associated with being a public company.

Sales and Marketing

Sales and marketing expense increased by $3.2 million to $5.6 million for the year ended December 31, 2021, compared to $2.3 million for the year ended December 31, 2020. This increase was primarily due to an increase of approximately $1.2 million in new marketing campaigns, updating marketing materials for investors and consumers, improving the Vivos website and promotion of conferences and events taking place in 2021, such as the Vivos Institute. Marketing expenses increased approximately $0.7 million due to various marketing initiatives as well as the deployment of SleepImage HST rings as demos to be used at different marketing events and marketing campaigns. Additionally, we had an increase of approximately $1.3 million in conference expenses as a result of conferences hosted in throughout the country and our August 2021 grand opening of The Vivos Institute in Denver, Colorado.

Settlement Expense

Settlement expense in 2020 resulted from the settlement of a shareholder demand in the fourth quarter of 2020. As a result of the settlement, we issued 300,000 shares of common stock with a fair value of $1.8 million and 325,000 warrants to purchase common shares with a fair value of $1.5 million. The aggregate settlement expense of $3.3 million was recognized for the year ended December 31, 2020 and we did not have a similar expense for the year ended December 31, 2021.

Impairment Loss

Impairment loss in 2021 resulted from the uncertainty of collection on a related party note receivable arising out of the sale of our company-owned dental facility in Orem, Utah in 2019. As a result, we impaired approximately $0.9 million as of December 31, 2021, and we did not have a similar expense for the year ended December 31, 2020.

Depreciation and Amortization

Depreciation and amortization expense was approximately $0.7 million for year ended December 31, 2021 and 2020. The impact of depreciation expense related to new assets placed into service was offset by lower depreciation expense related to legacy assets that were retired during the year. Our fixed assets placed in service increased by approximately $1.9 million in the year-over-year comparison primarily attributable to the buildout of our Vivos Institute facility in Denver, Colorado. These assets were placed into services at the beginning of August 2021. Accordingly, we expect to recognize higher depreciation and amortization expense in future periods.

Interest Expense

Interest expense decreased by approximately $0.1 million for the year ended December 31, 2021 as compared to the year ended December 31, 2020 as a result of convertible notes converted to Common Stock upon completion of our IPO in December 2020.

Interest Income

Interest income was unchanged at approximately $0.1 million for the year ended December 31, 2021 and 2020. Despite higher cash balances for the year ended December 31, 2021, the current low interest rate environment did not result in material earnings from temporary cash investments.

Liquidity and Capital Resources

As of December 31, 2021, we had cash and cash equivalents of $24.0 million compared to cash and cash equivalents of $18.2 million as of December 31, 2020. This increase was primarily driven by the net proceeds from our May 2021 underwritten follow-on offering, partially offset by spending during the year ended December 31, 2021. During the first quarter of 2021, we began tenant improvements to The Vivos Institute facility in Denver, Colorado, which we lease. The Vivos Institute facility opened in early August 2021 and provides onsite training courses and post-graduate education to our VIPs and other healthcare professionals.

While we have incurred losses and negative operating cash flows since inception, we believe that our existing cash resources following our May 2021 follow-on offering will be sufficient to meet our capital requirements and fund our planned operations for at least the next 18 months, although this estimation assumes we do not face unexpected events, costs, or contingencies, any of which could affect our liquidity and cash requirements. Available resources may be consumed more rapidly than anticipated, resulting in the need for additional funding if we do not generate positive cash flows from operations. If and when required, we anticipate funding our liquidity requirements from cash generated from operations and potentially from:

- proceeds from public and private financings (including equity (such as our "at the market offering" program through Roth Capital Partners), debt or equity-linked financings or commercial debt facilities);
- proceeds from the exercise of outstanding options or warrants; and
- strategic commercial transactions with third parties.

There is a risk that none of these plans will be implemented if and when necessary or on commercially reasonable terms, if at all, which could leave us without required cash resources and could adversely impact our results of operations and impair the viability of our company.

We do not have any off-balance sheet arrangements, as defined by applicable regulations of the SEC, that are reasonably likely to have a current or future material effect on our financial condition, results of operations, liquidity, capital expenditures or capital resources.

Cash Flows

The following table presents a summary of our cash flow for the years ended December 31, 2021 and 2020 (in thousands):

	2021	2020
Net cash provided by (used in):		
Operating activities	$ (15,735)	$ (5,680)
Investing activities	(2,608)	(120)
Financing activities	24,167	23,537

Net cash used in operating activities of approximately $15.7 million for the year ended December 31, 2021 is an increase of more than $10.0 million compared to net cash used in operating activities of approximately $5.7 million for the year ended December 31, 2020. This increase is due primarily to the increase in our net loss of approximately $8.2 million, an increase of approximately $0.5 million related to a tenant improvement allowance due to the company in 2022, $0.3 million in accounts receivable related to an increase in VIP enrollments during the two quarters of the year, an increase of approximately $0.6 million in accrued expenses due to increase in consulting fees, legal fees, and franchise tax, an increase of approximately $0.9 million in impairment for a related party note receivable arising from the 2019 sale of our company-owned dental clinic in Orem, Utah, an increase of approximately $0.8 million in prepaid expenses and current assets primarily driven by prepaid inventory for our SleepImage HST rings, deposits for future events including conferences and exhibits, and other prepaid services. Additionally, there was approximately a $0.5 million increase in contract liability due to the increase in VIP enrollments during the year ended December 31, 2021, compared to the year ended December 31, 2020.

For the year ended December 31, 2021, net cash used in investing activities consisted of (i) capital expenditures for property and equipment of $2.4 million, and cash payments for a business acquisition of $0.2 million, for a total of $2.6 million. Capital expenditures for property and equipment were primarily attributable to leasehold improvements for The Vivos Institute that opened in August 2021. For the year ended December 31, 2020, net cash used in investing activities amounted to $0.1 million for the purchase of equipment.

Net cash provided by financing activities of $24.2 million for the year ended December 31, 2021 was primarily attributable to proceeds of $25.4 million from the issuance of Common Stock in our follow-on public offering in May 2021 and proceeds from the exercise of stock options of $0.3 million. Total financing cash inflows amounted to $27.9 million gross and were partially offset by cash payments of $1.5 million for the redemption of all remaining shares of Series A Preferred Stock, and $2.2 million for professional fees and other offering costs related to our follow-on public offering, and principal payments under debt agreements of $0.1 million.

For the year ended December 31, 2020, net cash provided by financing activities of $23.5 million was primarily attributable to $22.3 million in cash proceeds from our initial public offering, $2.5 million in proceeds from the sale of Series B Preferred Stock, and $1.3 million in proceeds from the PPP loan. Total financing cash inflows amounted to $26 million and were partially offset by cash payments of $2.2 million for the redemption of shares of Series A Preferred Stock, $0.2 million for professional fees and other offering costs related to our initial public offering, and principal payments under debt agreements of $0.1 million.

Critical Accounting Policies Involving Management Estimates and Assumptions

Basis of Presentation and Consolidation

Our consolidated financial statements included as part of this Annual Report on Form 10-K, which include the accounts of our company and our wholly owned subsidiaries (BMS, First Vivos, Vivos Therapeutics (Canada) Inc., Vivos Management and Development, LLC and Vivos Del Mar Management, LLC), are prepared in conformity with U.S. GAAP and the rules and regulations of the SEC related to annual and quarterly reports. All significant intercompany balances and transactions have been eliminated in consolidation. Certain information and note disclosures normally included in annual financial statements prepared in accordance with U.S. GAAP have been condensed or omitted pursuant to those rules and regulations. The consolidated balance sheet as of December 31, 2020 included in this report has been derived from our audited consolidated financial statements.

Use of Estimates

To prepare financial statements in conformity with U.S. GAAP, management must make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

Concentration of Credit Risk and Significant Customers

Financial instruments, which potentially subject us to concentrations of credit risk, consist primarily of cash and cash equivalents and accounts receivable. We limit our exposure to credit loss by placing our cash with high credit quality financial institutions. Additionally, we have a diverse customer base and no single customer represented greater than ten percent of sales or accounts receivable for the years ended December 31, 2021 and 2020.

Accounts Receivable, Net

The accounts receivable in the accompanying consolidated financial statements are stated at the amounts management expects to collect. We reduce accounts receivable by estimating an allowance that may become uncollectible in the future. Management determines the estimated allowance for uncollectible amounts based on its judgements in evaluating the aging of the receivables and the financial condition of our clients. Allowance for uncollectible receivables was $0.2 million as of December 31, 2021 and $0.5 million as of December 31, 2020.

Intangible Assets, Net

Intangible assets consist of assets acquired from First Vivos and costs paid to MyoCorrect and Lyon Dental for work related to our patents, intellectual property and customer contracts. The identifiable intangible assets acquired from First Vivos and Lyon Dental for customer contracts are amortized using the straight-line method over the estimated life of the assets, which approximates 5 years (See Note 5). The costs paid to MyoCorrect and Lyon Dental for patents and intellectual property are amortized using the straight-line method over the life of the underlying patents, which approximates 15 years.

Goodwill

Goodwill is the excess of acquisition cost of an acquired entity over the fair value of the identifiable net assets acquired. Goodwill is not amortized but tested for impairment annually or whenever indicators of impairment exist. These indicators may include a significant change in the business climate, legal factors, operating performance indicators, competition, sale or disposition of a significant portion of the business or other factors. We test for impairment annually after the close of the year. There was no impairment of goodwill recognized at December 31, 2021 or 2020.

Long-lived Asset Policy

We review and evaluate the recoverability of long-lived assets whenever events or changes in circumstances indicate that an asset's carrying amount may not be recoverable. Such circumstances could include, but are not limited to, (1) a significant decrease in the market value of an asset, (2) a significant adverse change in the extent or manner in which an asset is used, or (3) an adverse action or assessment by a regulator. We measure the carrying amount of the asset against the estimated undiscounted future cash flows associated with it. Should the sum of the expected future net cash flows be less than the carrying value of the asset being evaluated, an impairment loss would be recognized. The impairment loss would be calculated as the amount by which the carrying value of the asset exceeds its fair value. The fair value is measured based on quoted market prices, if available. If quoted market prices are not available, the estimate of fair value is based on various valuation techniques, including the discounted value of estimated future cash flows. The evaluation of asset impairment requires us to make assumptions about future cash flows over the life of the asset being evaluated. These assumptions require significant judgment and actual results may differ from assumed and estimated amounts. Our evaluation of long-lived assets completed for the years ended December 31, 2021 and 2020 resulted in no impairment loss.

Notes Receivable, Net

The note receivable in the accompanying financial statements were stated at the amount management expected to collect. As of December 31, 2021, due to uncertainty of collections, we impaired the note receivable. To the extent cash is collected in the future we will recognize income in the period collected. The note receivable arose from the 2019 sales of our company-owned dental clinic in Oren, Utah.

Revenue Recognition

We generate revenue from the sale of products and services. Revenue is recognized when control of the products or services is transferred to our customers in a way that reflects the consideration we expect to be entitled to in exchange for those products and services.

We determine revenue recognition through the following five-step model, which entails:

1) identification of the promised goods or services in the contract;
2) determination of whether the promised goods or services are performance obligations, including whether they are distinct in the context of the contract;
3) measurement of the transaction price, including the constraint on variable consideration;
4) allocation of the transaction price to the performance obligations; and
5) recognition of revenue when, or as we satisfy each performance obligation.

Service revenue

We review our VIP contracts using the 5-step method outlined above. Once it is determined that a contract exists, service revenue is recognized when the underlying training or other services are performed. Unearned revenue reported on the balance sheet as contract liability represents the portion of fees paid by customers for services that have not yet been performed as of the reporting date and are recorded as the service is rendered. We recognize this revenue over the twelve-month life of the contract. Provisions for discounts are provided in the same period that the related revenue from the products and/or services is recorded.

We enter into programs that may provide for multiple element deliverables. Commencing in 2018, we began enrolling medical and dental professionals in a one-year program which included training in a highly personalized, deep immersion workshop format which provided the dentist access to an onboarding team who is dedicated to creating a successful integrated practice. The key topics covered in training included case selection, clinical diagnosis, appliance design, adjunctive therapies, instructions on ordering our products, guidance on pricing, instruction on insurance reimbursement protocols and interacting with our proprietary software system and the many features on our website. The initial training and educational workshop is typically provided in the first month that a VIP enrolls. Since VIPs are able to begin generating revenue after the first training workshop, we recognize 50% of the service revenue in the second month of enrollment and the remaining 50% pro-rata throughout the following eleven months of the service contract. Ongoing support and additional training are provided throughout the year and include access to our proprietary Airway Intelligence Service (or AIS) which provides VIPs with resources to help simplify the diagnostic and treatment planning process. AIS is provided as part of the price of each appliance and is not a separate revenue stream. Following the year of training and support, a VIP may pay for seminars and training courses that meet the VIP's needs on a subscription or a course by course basis.

In addition to enrollment service revenue, in 2020 we launched an additional service on a monthly subscription basis: Billing Intelligence Service (or BIS). Revenue for this service is recognized monthly during the month the service is rendered. Included in BIS is a monthly AirO2 license. In April 2021, we launched our MyoCorrect orofacial myofunctional therapy services.

We identify all goods and services that are delivered separately under a sales arrangement and allocate revenue to each deliverable based on relative fair values. Fair values are generally established based on the relevant service period which approximates the prices for relevant training that would be charged if those services were sold separately. In general, revenues are separated between durable medical equipment (product revenue) and education and training services (service revenue). The allocated revenue for each deliverable is then recognized ratably based on relative fair values of the components of the sale. Revenue from training is recognized over the relevant service period (i.e., as we satisfy our performance obligations and creates value for the VIP). We also evaluate the impact of undelivered items on the functionality of delivered items for each sales transaction and, where appropriate, defer revenue on delivered items when that functionality has been affected. Functionality is determined to be met if the delivered products or services represent a separate earnings process.

From time to time, we offer various discounts to our customers. These include the following:

1) Discount for cash paid in full
2) Conference and trade show incentives
3) Negotiated concessions on annual enrollment fee

The amount of the discount is determined up front prior to the sale. Accordingly, measurement is determined before the sale occurs and revenue is recognized based on the terms agreed upon between us and the VIP over the performance period. In rare circumstances, a discount has been given after the sale during a conference which is offering a discount to full price. In this situation revenue is measured and the change in transaction price is allocated over the remaining performance obligation.

The amount of consideration can vary by customer due to promotions and discounts authorized to incentivize a sale. Prior to the sale, the customer and us agree upon the amount of consideration that the customer will pay in exchange for the services we provide. The net consideration that the customer has agreed to pay is the expected value that is recognized as revenue over the service period. Any overpayments are refunded during the reporting period so that no refund liability is recognized. At the end of each reporting period, we update the transaction price to represent the circumstances present at the end of the reporting period and any changes in circumstances during the reporting period.

Product revenue

In addition to revenue from services, we also generate revenue from the sale of our patented oral devices (such as mmRNA and DNA appliances) and the Vivos Guides. Revenue from appliance sales is recognized when control of product is transferred to the VIP (our customer) in an amount that reflects the consideration we expect to be entitled to in exchange for those products. The VIP in turn charges the VIP's patient and/or patient's insurance a fee for the appliance and for his or her professional services in measuring, fitting, installing the appliance and educating the patient as to its use. We are contracted with the VIP for the sale of the appliance and are not involved in the sale of the products and services from the VIP to the VIP's patient.

Our appliances are visually similar to a retainer that is worn after braces are removed. Each appliance is specifically fitted to each patient. We utilize our network of certified VIPs throughout the country to sell the appliances to their customers as well as in two centers that we operate. We utilize third party contract manufacturers or labs to manufacture/fabricate each appliance and preformed Guide. The manufacturer designated by us (of which there are several) produces the appliance in strict adherence to our patents, design history files, protocols, processes and procedures and under the direction and specific instruction of us. The manufacturer then ships the appliance to the VIP who ordered the appliance through us. All of our contract manufacturers are required to follow our master design files in production of appliances, or the lab will be in violation of the FDA's rules and regulations. We performed an analysis under ASC Topic 606-10-55-36 through 55-40 and concluded it is the principal in the transaction and is reporting revenue gross. We bill the VIP provider the contracted price for the appliance which is recorded as product revenue. Product revenue is recognized once the appliance ships to the VIP provider under our direction.

Within each center, we utilize a team of medical professionals to measure, order and fit each appliance. Upon scheduling the patient (which is our customer in this case), the center takes a deposit and reviews the patient's insurance coverage. Revenue is recognized differently for our owned centers than for our VIPs. We recognize revenue in the centers after the appliance is received from the manufacturer and once the appliance is fitted and provided to the patient.

We offer our clinical advisors (who help our VIPs with the technical aspects of our products) discounts from our standard VIP pricing. In addition, from time to time, we offer buy one, get one offers and other credits to our VIPs to use our products and increase volume within their practices.

Stock-Based Compensation

Our board of directors (or the compensation committee thereof) grants share-based payments to employees under our equity incentive plans described below. We measure the cost of employee and director services received in exchange for all equity awards granted, including stock options, based on the fair market value of the award as of the grant date. We compute the fair value of stock options using the Black-Scholes-Merton ("BSM") option pricing model, and we estimate the expected term using the simplified method which is the average of the vesting term and the contractual term of the respective options. We then recognize the cost of the equity awards over the period that services are provided to earn the award, usually the vesting period. For awards granted which contain a graded vesting schedule, and the only condition for vesting is a service condition, compensation cost is recognized as an expense on a straight-line basis over the requisite service period as if the award were, in substance, a single award. We recognize the impact of forfeitures in the period that the forfeiture occurs, rather than estimating the number of awards that are not expected to vest in accounting for stock-based compensation. Prior to the commencement of public trading of our common stock in December 2020, we estimated fair value of our common stock based on the most recent sales to third parties. The assumptions used in our option pricing model represent management's best estimates. If factors change and different assumptions are used, our equity-based compensation expense could be materially different in the future. The key assumptions included in the model are as follows:

- Share Price – We use the closing price of our common stock on the grant date.
- Expected volatility — We determine the expected price volatility based on the historical volatilities of our peer group as we do not have a sufficient trading history for our common stock. Industry peers consist of several public companies in the bio-tech industry similar to us in size, stage of life cycle and financial leverage. We intend to continue to consistently apply this process using the same or similar public companies until a sufficient amount of historical information regarding the volatility of our own stock price becomes available, or unless circumstances change such that the identified companies are no longer similar to us, in which case, more suitable companies whose share prices are publicly available would be utilized in the calculation.
- Risk-free interest rate — The risk-free rate was determined based on yields of U.S. Treasury Bonds of comparable terms. The volatility is based on analyzing the stock price and implied volatility of guideline companies.
- Expected dividend yield — We have not previously issued dividends and do not anticipate paying dividends in the foreseeable future. Therefore, we used a dividend rate of zero based on our expectation of additional dividends.
- Expected term — We estimate the expected term using the simplified method which is the average of the vesting term and the contractual term of the options.

In 2017, our board of directors and shareholders approved the adoption of a stock and option award plan (the "2017 Plan"), under which shares were reserved for future issuance for options, restricted stock awards and other equity awards. The 2017 Plan permits grants of equity awards to employees, directors, consultants and other independent contractors. Our board of directors and shareholders approved a total reserve of 1,333,333 shares for issuance under the 2017 Plan.

In 2019, our board of directors and shareholders approved the adoption of a stock and option award plan (the "2019 Plan"), under which shares were reserved for future issuance for options, restricted stock awards and other equity awards. The 2019 Plan permits grants of equity awards to employees, directors, consultants and other independent contractors. Our board of directors and shareholders have approved a total reserve of 333,334 shares for issuance under the 2019 Plan. On June 18, 2020, our shareholders approved an amendment and restatement of the 2019 Plan to increase the number shares or our common stock available for issuance thereunder by 833,333 share of common stock such that, after amendment and restatement of the 2019 Plan, and prior to any grants, 1,166,667 shares of common stock were available under the 2019 Plan. On July 28, 2021, our stockholders approved an amendment and restatement of the 2019 Plan to increase the number of shares of common stock available for issuance thereunder by 1,200,000 shares of common stock such that, after amendment and restatement of the 2019 Plan, and prior to any grants, 2,366,667 shares of common stock were available under the 2019 Plan.

Basic and Diluted Net Loss Per Share

Basic net loss per share is computed using the weighted average number of common shares outstanding during the period. Diluted net loss per common share is computed using the weighted average number of common shares outstanding and the weighted average dilutive potential common shares outstanding using the treasury stock method. However, for the years ended December 31, 2021 and 2020, diluted net loss per share is the same as basic net loss per share as the inclusion of weighted average shares of common stock issuable upon the exercise of outstanding warrants and stock options would be anti-dilutive. The numerator in the basic and diluted net loss per share calculation is the net loss attributable to common stockholders, which is the net loss for the year increased by the current year preferred stock dividends accrued.

The holder of our formerly outstanding Series A Preferred Stock (Dr. G. Dave Singh, our founder and former Chief Medical Officer) was entitled to participate in common stock dividends, if and when declared, on a one-to-one per-share basis. Accordingly, in periods in which we have net income, earnings per share will be computed using the two-class method whereby the pro rata dividends distributable to the holder of our Series A Preferred Stock will be deducted from earnings applicable to common stockholders, regardless of whether a dividend is declared for such undistributed earnings. For the years ended December 31, 2021 and 2020, we incurred a net loss and, accordingly, there were no undistributed earnings to allocate under the two-class method.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board or other standard setting bodies that are adopted by us as of the specified effective date. Unless otherwise discussed in Note 1 to our consolidated financial statements included in Item 8 of this Report, we believe that the impact of recently issued standards that are not yet effective could have a material impact on our financial position or results of operations upon adoption. For additional information on recently issued accounting standards and our plans for adoption of those standards, please refer to the section titled *Recent Accounting Pronouncements* under Note 1 to our consolidated financial statements included in Item 8 of this Report.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Trade Policy Risk. Certain of our products or components are manufactured outside the United States. Most products imported into the United States is subject to duty and restrictive quotas on the amount of products that can be imported from certain countries into the United States each year. Because of the duty rates and quotas, changes in U.S. trade policy as reflected in various legislation, trade preference programs and trade agreements have the potential to materially impact our sourcing strategy and the competitiveness of its contract manufacturers. We manage this risk by continually monitoring U.S. trade policy, analyzing the impact of changes in such policy and adjusting its manufacturing and sourcing strategy accordingly.

Foreign Currency Risk. We receive United States dollars for all of our product sales. Currently, all inventory purchases from our non-U.S. contract manufacturers are also denominated in United States dollars; however, should we make purchases in foreign currencies in the future, purchase prices for our products may be impacted by fluctuations in the exchange rate between the United States dollar, which may have the effect of increasing our cost of goods in the future.

Commodity Price Risk. We are subject to commodity price risk arising from price fluctuations in the market prices of sourced titanium and steel products or the various raw materials components of its manufactured products. We are subject to commodity price risk to the extent that any fluctuations in the market prices of its purchased titanium and steel products and raw materials are not reflected by adjustments in selling prices of its products or if such adjustments significantly trail changes in these costs. We neither enter into significant long-term sales contracts nor enter into significant long-term purchase contracts. We do not engage in hedging activities with respect to such risk.

Credit Risk. Credit risk relates to the risk of loss resulting from non-performance or non-payment by counterparties pursuant to the terms of their contractual obligations. Risks surrounding counterparty performance and credit could ultimately impact the amount and timing of expected cash flows. Certain financial instruments potentially subject our company to a concentration of credit risk. These financial instruments consist primarily of cash and cash equivalents and accounts and vendor receivables. We place our cash and cash equivalents with high-credit, quality financial institutions. The balances in these accounts exceed the amounts insured by the Federal Deposit Insurance Corporation.

Item 8. Financial Statements and Supplementary Data.

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Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors of
Vivos Therapeutics, Inc. and Subsidiaries

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Vivos Therapeutics, Inc. and Subsidiaries (the "Company"), as of December 31, 2021 and 2020 and the related statements of operations, stockholders' equity (deficit), and cash flows for each of the years in the two-year period ended December 31, 2021, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2021 and 2020, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2021, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

The Company's management is responsible for these financial statements. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Plante & Moran, PLLC

We have served as the Company's auditor since 2018.

Denver, Colorado
March 31, 2022

VIVOS THERAPEUTICS INC.
Consolidated Balance Sheets
December 31, 2021 and 2020
(In Thousands, Except Per Share Amounts)

	2021	2020
ASSETS		
Current assets		
Cash and cash equivalents	$ 24,030	$ 18,206
Accounts receivable, net of allowance of $180 and $508, respectively	1,203	1,431
Current portion of note receivable from related party	-	84
Tenant improvement allowance receivable	516	-
Prepaid expenses and other current assets	1,575	673
Total current assets	27,324	20,394
Long-term assets		
Goodwill	2,843	2,671
Property and equipment, net	2,825	872
Note receivable from related party, net of current portion	-	811
Intangible assets, net	341	270
Deposits and other	356	309
Total assets	$ 33,689	$ 25,327
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 920	$ 781
Payable to related party for redemption of Series A Preferred Stock	-	1,500
Accrued expenses	2,853	1,737
Contract liabilities	2,399	2,938
Current portion of long-term debt	1,265	867
Current portion of deferred rent	3	18
Current portion of lease incentive liability	69	-
Total current liabilities Total current liabilities	7,509	7,841
Long-term liabilities		
Long-term debt, net of current maturities	-	423
Deferred rent, net of current portion	343	146
Lease incentive liability, net of current portion	298	-
Total liabilities Total liabilities	8,150	8,410
Commitments and contingencies (Note 13)		
Stockholders' equity		
Preferred Stock, $0.0001 par value per share. Authorized 50,000,000 shares; no shares issued and outstanding	-	-
Common Stock, $0.0001 par value per share. Authorized 200,000,000 shares; issued and outstanding 23,012,119 and 18,209,452 shares as of December 31, 2021 and 2020, respectively	2	2
Additional paid-in capital	81,160	52,250
Accumulated deficit	(55,623)	(35,335)
Total stockholders' deficit Total stockholders' equity	25,539	16,917
Total liabilities and stockholders' deficit Total liabilities and stockholders' equity	$ 33,689	$ 25,327

The accompanying notes are an integral part of these consolidated financial statements.

VIVOS THERAPEUTICS INC.
Consolidated Statements of Operations
Years Ended December 31, 2021 and 2020
(In Thousands, Except Per Share Amounts)

	2021	2020
Revenue		
Product revenue	$ 6,520	$ 4,890
Service revenue	10,365	8,176
Total revenue	16,885	13,066
Cost of sales (exclusive of depreciation and amortization shown separately below)	4,281	2,653
Gross profit	12,604	10,413
Operating expenses		
General and administrative	25,791	16,090
Sales and marketing	5,551	2,314
Litigation settlement	-	3,331
Impairment loss	911	-
Depreciation and amortization	733	718
Total operating expenses	32,986	22,453
Operating loss	(20,382)	(12,040)
Non-operating income (expense)		
Interest expense	(14)	(96)
Other expense	(9)	-
Interest income	117	79
Loss before income taxes	(20,288)	(12,057)
Income tax expense	-	-
Net loss	$ (20,288)	$ (12,057)
Warrant beneficial conversion feature	-	(3,598)
Preferred stock accretion	-	(2,333)
Net loss attributable to common stockholders	$ (20,288)	$ (17,988)
Net loss per share attributable to common stockholders (basic and diluted)	$ (0.96)	$ (1.40)
Weighted average number of shares of Common Stock outstanding (basic and diluted)	21,233	12,869

The accompanying notes are an integral part of these consolidated financial statements.

VIVOS THERAPEUTICS INC.
Consolidated Statements of Stockholders' Equity (Deficit)
Years Ended December 31, 2021 and 2020
(In Thousands)

	Common Stock		Series B Preferred		Additional Paid-in	Accumulated	
	Shares	Amount	Units	Amount	Capital	Deficit	Total
Balances, December 31, 2019	12,444,165	$ 1	-	$ -	$ 20,334	$ (23,278)	$ (2,943)
Series B preferred stock issued:							
For cash, net of issuance costs	-	-	164	2,403	-	-	2,403
In exchange for convertible debt	-	-	196	2,944	-	-	2,944
Issuance of Common Stock:							
For exchange of Series B preferred stock	1,199,195	1	(360)	(5,347)	5,346	-	-
In initial public offering, net of issuance costs	4,025,000	-	-	-	21,577	-	21,577
To consultants for services	88,111	-	-	-	677	-	677
For settlement of liability	46,667	-	-	-	350	-	350
For conversion of convertible debt	106,314	-	-	-	796	-	796
In litigation settlement	300,000	-	-	-	1,800	-	1,800
Fair value of warrants issued in litigation settlement	-	-	-	-	1,531	-	1,531
Stock-based compensation expense	-	-	-	-	2,172	-	2,172
Series A preferred stock accretion	-	-	-	-	(2,333)	-	(2,333)
Net loss	-	-	-	-	-	(12,057)	(12,057)
Balances, December 31, 2020	18,209,452	2	-	-	52,250	(35,335)	16,917
Issuance of Common Stock:							
In follow-on public offering, net of issuance costs	4,600,000	-			25,362	-	25,362
To consultants for services	2,667	-	-	-	20	-	20
Upon exercise of stock options	200,000	-	-	-	330	-	330
Fair value of warrants issued:							
To consultants for services	-	-	-	-	232	-	232
In business combination	-	-	-	-	172	-	172
For purchase of assets	-	-	-	-	136	-	136
Stock-based compensation expense	-	-	-	-	2,658	-	2,658
Net loss	-	-	-	-	-	(20,288)	(20,288)
Balances, December 31, 2021	23,012,119	$ 2	-	$ -	$ 81,160	$ (55,623)	$ 25,539

The accompanying notes are an integral part of these consolidated financial statements.

VIVOS THERAPEUTICS INC.
Consolidated Statements of Cash Flows
Years Ended December 31, 2021 and 2020
(In Thousands)

	2021	2020
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (20,288)	$ (12,057)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	2,658	2,172
Depreciation and amortization	733	718
Fair value of warrants issued for services	232	-
Common stock issued for services and settlement of liabilities	20	488
Accretion of discount on note receivable	(29)	(26)
Impairment on note receivable	911	
Common stock issued in litigation settlement	-	1,925
Fair value of warrants issued in litigation settlement	-	1,531
Changes in operating assets and liabilities:		
Accounts receivable	228	(560)
Deferred rent and lease incentive liability	548	80
Tenant improvement allowance	(516)	
Prepaid expenses and other current assets	(902)	(114)
Deposits	(47)	(27)
Accounts payable	139	(274)
Accrued expenses	1,117	474
Contract liability	(539)	(10)
Net cash used in operating activities	(15,735)	(5,680)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Acquisitions of property and equipment	(2,396)	(120)
Payment for business acquisition	(225)	-
Principal collections under note receivable	13	-
Net cash used in investing activities	(2,608)	(120)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock	27,930	22,290
Series A Preferred Stock redemption payments	(1,500)	(2,150)
Payments for issuance costs	(2,238)	(245)
Principal payments on debt	(25)	(75)
Proceeds from issuance of preferred stock	-	2,452
Proceeds from issuance of debt	-	1,265
Net cash provided by financing activities	24,167	23,537
Net increase in cash and cash equivalents	5,824	17,737
Cash and cash equivalents at beginning of year	18,206	469
Cash and cash equivalents at end of year	$ 24,030	$ 18,206
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:		
Cash paid for interest	$ 18	$ 33
Cash paid for income taxes	$ -	$ -
SUPPLEMENTAL DISCLOSURE OF NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Fair value of warrants issued in asset purchase	$ 136	$ -
Fair value of warrants issued in business acquisition	$ 172	-
Fair value of warrants issued to underwriters in connection with follow-on offering	$ 1,486	$ -
Conversion of debt to common stock	$ -	$ 770
Exchange of debt to Series B preferred stock	$ -	$ 2,944
Exchange of Series B preferred stock into common shares	$ -	$ 5,347
Common stock issued for payment of interest	$ -	$ 26
Series B Preferred Stock issued for payment of interest	$ -	$ 102
Series A Preferred Stock redemption included in accounts payable	$ -	$ 1,500
Capital expenditures included in accounts payable	$ 110	$ 2

The accompanying notes are an integral part of these consolidated financial statements.

VIVOS THERAPEUTICS INC.
Notes to Consolidated Financial Statements

NOTE 1 - ORGANIZATION, DESCRIPTION AND SIGNIFICANT ACCOUNTING POLICIES

Organization

BioModeling Solutions, Inc. ("BioModeling") was organized on March 20, 2007 as an Oregon limited liability company, and subsequently incorporated in 2013. On August 16, 2016, BioModeling entered into a share exchange agreement (the "SEA") with First Vivos, Inc. ("First Vivos"), and Vivos Therapeutics, Inc. ("Vivos"), a Wyoming corporation established on July 7, 2016 to facilitate this merger. Vivos was formerly named Corrective BioTechnologies, Inc. until its name changed on September 6, 2016 to Vivos Biotechnologies and on March 2, 2018 to Vivos Therapeutics, Inc. and had no substantial pre-combination business activities. First Vivos was incorporated in Texas on November 10, 2015. Pursuant to the SEA, all of the outstanding shares of common stock and warrants of BioModeling and all of the shares of commons stock of First Vivos were exchanged for newly issued shares of Class A common stock and warrants of Vivos, the legal acquirer, collectively the "Company".

The transaction was accounted for as a reverse acquisition and recapitalization, with BioModeling as the acquirer for financial reporting and accounting purposes. Upon the consummation of the merger, the historical financial statements of BioModeling became the Company's historical financial statements and continued to be recorded at their historical carrying amounts.

On August 12, 2020, the Company reincorporated from Wyoming to become a domestic Delaware corporation under Delaware General Corporate Law.

Description of Business

The Company is a medical technology company focused on the development and commercialization to dental practices of a patented oral appliance technology and related protocols called The Vivos Method. The Company believes The Vivos Method represents the first non-surgical, non-invasive and cost-effective treatment for people with dentofacial abnormalities and/or mild to moderate OSA and snoring. The Company's business model is focused around dentists, and the Company's program to train dentists and offer them other value-added services in connection with their ordering and use of The Vivos Method for patients is called the Vivos Integrated Practice ("VIP") program.

Basis of Presentation and Consolidation

The accompanying consolidated financial statements, which include the accounts of the Company and its wholly owned subsidiaries (BioModeling, First Vivos, Vivos Therapeutics (Canada) Inc., Vivos Management and Development, LLC and Vivos Del Mar Management, LLC), are prepared in conformity with generally accepted accounting principles in the United States of America ("U.S. GAAP"). All significant intercompany balances and transactions have been eliminated in consolidation.

Emerging Growth Company

The Company is an "emerging growth company," as defined in Section 2(a) of the Securities Act, as modified by the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"), and it may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act"), reduced disclosure obligations regarding executive compensation, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

Further, Section 102(b)(1) of the JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies (that is, those that have not had a Securities Act registration statement declared effective or do not have a class of securities registered under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) are required to comply with the new or revised financial accounting standards. The JOBS Act provides that a company can elect to opt out of the extended transition period and comply with the requirements that apply to non-emerging growth companies but any such election to opt out is irrevocable. The Company currently expects to retain its status as an emerging growth company until the year ending December 31, 2026, but this status could end sooner under certain circumstances.

Revenue Recognition

The Company generates revenue from the sale of products and services. Revenue is recognized when control of the products or services is transferred to our customers in a way that reflects the consideration we expect to be entitled to in exchange for those products and services.

The Company determines revenue recognition through the following five-step model, which entails:

1) identification of the promised goods or services in the contract;
2) determination of whether the promised goods or services are performance obligations, including whether they are distinct in the context of the contract;
3) measurement of the transaction price, including the constraint on variable consideration;
4) allocation of the transaction price to the performance obligations; and
5) recognition of revenue when, or as the Company satisfies each performance obligation.

Service revenue

We review our VIP contracts using the 5-step method outlined above. Once it is determined that a contract exists, service revenue is recognized when the underlying training or other services are performed. Unearned revenue reported on the balance sheet as contract liability represents the portion of fees paid by customers for services that have not yet been performed as of the reporting date and are recorded as the service is rendered. The Company recognizes this revenue over the twelve-month life of the contract. Provisions for discounts are provided in the same period that the related revenue from the products and/or services is recorded.

The Company enters into programs that may provide for multiple element deliverables. Commencing in 2018, the Company began enrolling medical and dental professionals in a one-year program which includes training in a highly personalized, deep immersion workshop format which provides the dentist access to a global team who is dedicated to creating a successful integrated practice. The key topics covered in training include case selection, clinical diagnosis, appliance design, adjunctive therapies, instructions on ordering the Company's products, guidance on pricing, instruction on insurance reimbursement protocols and interacting with our proprietary software system and the many features on the Company's website. The initial training and educational workshop is typically provided in the first month that a Vivos Integrated Provider ("VIP" or "Provider") enrolls. Since Providers are able to begin generating revenue after the first training workshop, we recognize 50% of the service revenue in the second month of enrollment and the remaining 50% prorata throughout the following eleven months of the service contract. Ongoing support and additional training is provided throughout the year and includes access to the Company's proprietary Airway Intelligence Service ("AIS") which provides the Provider with resources to help simplify the diagnostic and treatment planning process. AIS is provided as part of the price of each appliance and is not a separate revenue stream. Following the year of training and support, the Provider may pay for seminars and training courses that meet the Provider's needs on a subscription or a course-by-course basis.

In addition to enrollment service revenue, in 2020 the Company launched an additional service on a monthly subscription basis, its Billing Intelligence Service ("BIS"). Revenue for these services is recognized monthly during the month the services are rendered.

The Company identifies all goods and services that are delivered separately under a sales arrangement and allocates revenue to each deliverable based on relative fair values. Fair values are generally established based on the relevant service period which approximates the prices for relevant training that would be charged if those services were sold separately. In general, revenues are separated between durable medical equipment (product revenue) and education and training services (service revenue). The allocated revenue for each deliverable is then recognized ratably based on relative fair values of the components of the sale. Revenue from training is recognized over the relevant service period, i.e., as the Company satisfies its performance obligations and creates value for the Provider. The Company also evaluates the impact of undelivered items on the functionality of delivered items for each sales transaction and, where appropriate, defers revenue on delivered items when that functionality has been affected. Functionality is determined to be met if the delivered products or services represent a separate earnings process.

From time to time, we offer various discounts to our customers. These include the following:

1) Discount for cash paid in full
2) Conference or trade show incentives
3) Negotiated concessions on annual enrollment fee

The amount of the discount is determined up front prior to the sale. Accordingly, measurement is determined before the sale occurs and revenue is recognized based on the terms agreed upon between the Company and the customer over the performance period. In rare circumstances, a discount has been given after the sale during a conference which is offering a discount to full price. In this situation revenue is measured and the change in transaction price is allocated over the remaining performance obligation.

The amount of consideration can vary by customer due to promotions and discounts authorized to incentivize a sale. Prior to the sale, the customer and the Company agree upon the amount of consideration that the customer will pay in exchange for the services the Company provides. The net consideration that the customer has agreed to pay is the expected value that is recognized as revenue over the service period. Any overpayments are refunded during the reporting period so that no refund liability is recognized. At the end of each reporting period, the Company updates the transaction price to represent the circumstances present at the end of the reporting period and any changes in circumstances during the reporting period.

Product revenue

In addition to revenue from services, the Company also generates revenue from the sale of its patented oral devices and preformed guides, known as appliances or systems to its customer, the Provider. Revenue from the appliance sale is recognized when control of product is transferred to the Provider in an amount that reflects the consideration it expects to be entitled to in exchange for those products. The Provider in turn charges the Provider's patient and or patient's insurance a fee for the appliance and for his or her professional services in measuring, fitting, installing the appliance and educating the patient as to its use. The Company is contracted with the Provider for the sale of the appliance and is not involved in the sale of the products and services from the Provider to the Provider's patient.

The appliance is similar to a retainer that is worn after braces are removed. Each appliance is unique and is fitted to the patient. The Company utilizes its network of certified dental Providers throughout the country to sell the appliances to their customers as well as in two centers that the Company operates. The Company utilizes third party contract manufacturers or labs to produce its unique, patented appliances and preformed guides. The manufacturer designated by the Company produces the appliance in strict adherence to the Company's patents, design files, protocols, processes and procedures and under the direction and specific instruction of the Company, ships the appliance to the Provider who ordered the appliance from the Company. All of the Company's contract manufacturers are required to follow the Company's master design files in production of appliances or the lab will be in violation of the FDA's rules and regulations. The Company performed an analysis under ASC Topic 606-10-55-36 through 55-40 and concluded it is the principal in the transaction and is reporting revenue gross. The Company bills the Provider the contracted price for the appliance which is recorded as product revenue. Product revenue is recognized once the appliance ships to the Provider under the direction of the Company.

Within each center, the Company utilizes a team of medical professionals to measure, order and fit each appliance. Upon scheduling the patient (which is the Company's customer in this case), the center takes a deposit and reviews the patient's insurance coverage. Revenue is recognized differently for our Company owned centers than for its Providers. The Company recognizes revenue in the centers after the appliance is received from the manufacturer and once the appliance is fitted and provided to the patient.

The Company offers its Clinical Advisors discounts from our standard Provider pricing. This is done to help encourage our Clinical Advisors, who help the Provider with technical aspects of our products, to purchase our products for their own practices. In addition, from time to time, we offer buy one get one offers and other credits to incentivize our Providers to embrace our products and increase volume within their practices.

Use of Estimates

The preparation of financial statements and related disclosures in conformity with U.S. GAAP requires the Company to make judgments, assumptions, and estimates that affect the amounts reported in its consolidated financial statements and accompanying notes. The Company bases its estimates and assumptions on existing facts, historical experience, and various other factors that it believes are reasonable under the circumstances, to determine the carrying values of assets and liabilities that are not readily apparent from other sources. The Company's significant accounting estimates include, but are not necessarily limited to, assessing collectability on accounts receivable and notes receivable, impairment of goodwill and long-lived assets; valuation assumptions for assets acquired in business combinations; valuation assumptions for stock options, warrants and equity instruments issued for goods or services; deferred income taxes and the related valuation allowances; and the evaluation and measurement of contingencies. Additionally, the full impact of COVID-19 is unknown and cannot be reasonably estimated. However, the Company has made appropriate accounting estimates based on the facts and circumstances available as of the reporting date. To the extent there are material differences between the Company's estimates and the actual results, the Company's future consolidated results of operations will be affected.

Cash and Cash Equivalents

All highly liquid investments purchased with an original maturity of three months or less that are freely available for the Company's immediate and general business use are classified as cash and cash equivalents.

Accounts Receivable, Net

The accounts receivable in the accompanying financial statements are stated at the amounts management expects to collect. The Company performs credit evaluations of its customers' financial condition and may require a prepayment for a portion of the services to be performed. The Company reduces accounts receivable by estimating an allowance that may become uncollectible in the future. Management determines the estimated allowance for uncollectible amounts based on its judgements in evaluating the aging of the receivables and the financial condition of our clients.

Note Receivable from Related Party, net

Due to uncertainty around collections, the note receivable due from a related party was impaired as of December 31, 2021. To the extend cash is collected in the future, we will recognize income in the period cash is collected.

Property and Equipment, Net

Property and equipment are stated at historical cost less accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful lives of the assets, which ranges from 4 to 5 years. Amortization of leasehold improvements is recognized using the straight-line method over the shorter of the life of the improvement or the term of the respective leases which range between 5 and 7 years. The Company does not begin depreciating assets until they are placed in service.

Intangible Assets, Net

Intangible assets consist of assets acquired from First Vivos and costs paid to OMT and Lyon Dental for work related to the Company's patents, intellectual property and customer contracts. The identifiable intangible assets acquired from First Vivos and Lyon Dental for customer contracts are amortized using the straight-line method over the estimated life of the assets, which approximates 5 years (See Note 5). The costs paid to OMT and Lyon Dental for patents and intellectual property are amortized over the life of the underlying patents, which approximates 15 years. The Company initially determined the fair value of identifiable intangible assets using a discounted cash flow valuation model.

Goodwill

Goodwill represents the excess of the purchase price of acquired businesses over the estimated fair value of the identifiable net assets acquired. Goodwill is not amortized but tested for impairment annually after the close of the year, or more frequently when events or circumstances indicate that the carrying value of a reporting unit more likely than not exceeds its fair value. The goodwill impairment test is applied by performing a qualitative assessment before calculating the fair value of the reporting unit. If, on the basis of qualitative factors, it is considered more likely than not that the fair value of the reporting unit is greater than the carrying amount, further testing of goodwill for impairment is not required. If, on the basis of quantitative factors, the carrying amount of a reporting unit exceeds the reporting unit's fair value, an impairment loss is recognized in an amount equal to that excess, limited to the total amount of goodwill allocated to that reporting unit.

Impairment of Long-lived Assets

Long-lived assets consist of identifiable intangible assets, property and equipment, which are reviewed for impairment whenever events or changes in circumstances indicate the carrying amount of an asset may not be recoverable. Impairment exists for long-lived assets if the carrying amounts of such assets exceed the estimates of future net undiscounted cash flows expected to be generated by such assets. An impairment charge is recognized for the amount by which the carrying amount of the asset, or asset group, exceeds its fair value.

Equity Offering Costs

Commissions, legal fees and other costs that are directly associated with equity offerings are capitalized as deferred offering costs, pending a determination of the success of the offering. Deferred offering costs related to successful offerings are charged to additional paid-in capital in the period it is determined that the offering was successful. Deferred offering costs related to unsuccessful equity offerings are recorded as expense in the period when it is determined that an offering is unsuccessful.

Accounting for Payroll Protection Program Loan

The Company is accounting for the PPP loan as a debt instrument under ASC 470, *Debt*. The Company recognized the original principal balance as a financial liability with interest accrued at the contractual rate over the term of the loan. On January 21, 2022 the PPP loan received by the Company on May 8, 2020, was forgiven by the SBA in its entirety, which includes approximately $1.3 million in principal. As a result, the Company will record a gain on the forgiveness of the loan in the first quarter of 2022.

Loss and Gain Contingencies

The Company is subject to the possibility of various loss contingencies arising in the ordinary course of business. An estimated loss contingency is accrued when it is probable that an asset has been impaired, or a liability has been incurred, and the amount of loss can be reasonably estimated. If some amount within a range of loss appears to be a better estimate than any other amount within the range, the Company accrues that amount. Alternatively, when no amount within a range of loss appears to be a better estimate than any other amount, the Company accrues the lowest amount in the range. If the Company determines that a loss is reasonably possible and the range of the loss is estimable, then the Company discloses the range of the possible loss. If the Company cannot estimate the range of loss, it will disclose the reason why it cannot estimate the range of loss. The Company regularly evaluates current information available to it to determine whether an accrual is required, an accrual should be adjusted and if a range of possible loss should be disclosed. Legal fees related to contingencies are charged to general and administrative expense as incurred. Contingencies that may result in gains are not recognized until realization is assured, which typically requires collection in cash.

Share-Based Compensation

The Company measures the cost of employee and director services received in exchange for all equity awards granted, including stock options, based on the fair market value of the award as of the grant date. The Company computes the fair value of stock options using the Black-Scholes-Merton ("BSM") option pricing model. The Company estimates the expected term using the simplified method which is the average of the vesting term and the contractual term of the respective options. The Company determines the expected price volatility based on the historical volatilities of their peer group as the Company does not have a sufficient trading history for their common stock. Industry peers consist of several public companies in the bio-tech industry similar to the Company in size, stage of life cycle and financial leverage. The Company intends to continue to consistently apply this process using the same or similar public companies until a sufficient amount of historical information regarding the volatility of our own stock price becomes available, or unless circumstances change such that the identified companies are no longer similar to Vivos, in which case, more suitable companies whose share prices are publicly available would be utilized in the calculation. The Company recognizes the cost of the equity awards over the period that services are provided to earn the award, usually the vesting period. For awards granted which contain a graded vesting schedule, and the only condition for vesting is a service condition, compensation cost is recognized as an expense on a straight-line basis over the requisite service period as if the award were, in substance, a single award. The Company recognizes the impact of forfeitures in the period that the forfeiture occurs, rather than estimating the number of awards that are not expected to vest in accounting for stock-based compensation. Prior to public trading of the Company's shares which commenced in December 2020, the Company estimated fair value of its shares based on the most recent sales to third parties.

Income Taxes

The Company accounts for income taxes in accordance with Accounting Standards Codification ("ASC") 740, Income Taxes, under which deferred income taxes are recognized based on the estimated future tax effects of differences between the financial statement and tax bases of assets and liabilities given the provisions of enacted tax laws. Deferred income tax provisions and benefits are based on changes to the assets or liabilities from year to year. In providing for deferred taxes, the Company considers tax regulations of the jurisdictions in which the Company operates, estimates of future taxable income, and available tax planning strategies. If tax regulations, operating results, or the ability to implement tax-planning strategies vary, adjustments to the carrying value of deferred tax assets and liabilities may be required. A valuation allowance is recorded when it is more likely than not that a deferred tax asset will not be realized. The recorded valuation allowance is based on significant estimates and judgments and if the facts and circumstances change, the valuation allowance could materially change. In accounting for uncertainty in income taxes, the Company recognizes the financial statement benefit of a tax position only after determining that the relevant tax authority would more likely than not sustain the position following an audit. For tax positions meeting the more likely than not threshold, the amount recognized in the financial statements is the largest benefit that has a greater than 50 percent likelihood of being realized upon ultimate settlement with the relevant tax authority. The Company recognizes interest and penalties accrued on any unrecognized tax benefits as a component of income tax expense.

Basic and Diluted Net Loss Per Share

Basic net loss per common share is computed by dividing the net loss applicable to common stockholders by the weighted average number of common shares outstanding for each period presented. Diluted net loss per common share is computed by giving effect to all potential shares of Common Stock, including stock options, convertible debt, Preferred Stock, and warrants, to the extent dilutive.

Recent Accounting Pronouncements

Presented below is a discussion of new accounting standards including deadlines for adoption assuming that the Company retains its designation as an EGC.

Standards Required to be Adopted in Future Years. The following accounting standards are not yet effective as of December 31, 2021.

In February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2016-02, *Leases* (Topic 842). This ASU requires the Company to recognize lease assets and lease liabilities on the balance sheet and also disclose key information about leasing arrangements. In July 2018, the FASB issued ASU No. 2018-11 *Targeted Improvements*, which provides lessees the option to adopt either (i) retrospectively to each prior reporting period presented upon initial adoption, or (ii) apply the new leasing standard to all open leases as of the adoption date by recognizing a cumulative-effect adjustment to accumulated deficit in the period of adoption without restating prior periods. The Company adopted the new accounting standard on January 1, 2022, this adoption required the company to recognize a current and long-term lease liability of approximately within the range of $2.4 million to $2.2 million and a right-of-use (ROU) asset of approximately within the range of $1.7 million to $1.5 million. We applied the new lease standard to all open leases as of the adoption date, with no retrospective adjustments to prior comparative periods.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments.* ASU 2016-13 amends the guidance on the impairment of financial instruments. This guidance requires use of an impairment model (known as the "current expected credit losses", or CECL model) that is based on expected losses rather than incurred losses. Under the new guidance, an entity recognizes, as an allowance, its estimate of expected credit losses. ASU 2016-13 is effective for the Company beginning in the first quarter of 2023. The Company is still evaluating the impact the adoption of ASU 2016-13 will have on its results of operations or financial position.

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740), Simplifying the Accounting for Income Taxes*, which is intended to simplify various aspects related to accounting for income taxes. ASU 2019-12 removes certain exceptions to the general principles in Topic 740 and clarifies and amends existing guidance to improve consistent application. ASU 2019-12 is effective for the Company beginning in the first quarter of 2022. Early adoption is permitted, including adoption in an interim period. The adoption of this standard did not have a material impact on the Company's consolidated financial statements.

Other accounting standards that have been issued or proposed by the FASB or other standards-setting bodies that do not require adoption until a future date are not currently expected to have a material impact on the Company's financial statements upon adoption.

Recently Adopted Standards. The following recently issued accounting standards were adopted by the Company during the year ended December 31, 2021:

In August 2020, the FASB issued ASU 2020-06, *Debt – Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity).* ASU 2020-06 reduces the number of accounting models for convertible debt instruments and convertible preferred stock, which results in fewer embedded conversion features being separately recognized from the host contract as compared with current GAAP. Additionally, ASU 2020-06 affects the diluted earnings per share calculation for instruments that may be settled in cash or shares and for convertible instruments and requires enhanced disclosures about the terms of convertible instruments and contracts in an entity's own equity. Effective January 1, 2021, the Company elected to adopt ASU 2020-06 using the modified retrospective transition method which did not result in any changes to the Company's financial statements upon adoption.

NOTE 2 – LIQUIDITY

As of December 31, 2021, the Company had an accumulated deficit of $55.6 million. For the years ended December 31, 2021 and 2020, the Company incurred a net loss of $20.3 and $12.1 million, respectively. Net cash used in operating activities amounted to $15.7 million and $5.7 million for the years ended December 31, 2021 and 2020, respectively. Since March 2020, the Company's business has been negatively impacted as a result of the COVID-19 pandemic. Revenue growth and collections in 2021 were impacted by significant headwinds throughout the Company's core customer base, mostly driven by COVID-19 Delta and Omicron variant resurgences in the middle and latter part of the year as discussed in Note 13.

As discussed in Note 9, in December 2020 the Company completed an IPO of approximately 4.0 million shares of Common Stock for net proceeds of approximately $21.6 million, and in May 2021, the Company completed a follow-on underwritten public offering of 4.6 million shares of Common Stock for net proceeds of approximately $25.4 million. As of December 31, 2021, the Company has cash and cash equivalents of $24.0 million and total liabilities of $8.1 million.

Management believes the Company's existing cash resources will be sufficient to fund the Company's contractual obligations and working capital requirements at least through the first quarter of 2023.

NOTE 3 – RECEIVABLES, CONTRACT ASSETS AND CONTRACT LIABILITIES

Net Revenue

For the years ended December 31, 2021 and 2020, the components of revenue from contracts with customers and the related timing of revenue recognition is set forth in the table below (in thousands):

	Year Ended December 31,	
	2021	**2020**
Product revenue:		
Appliance sales to VIPs	$ 6,040[1]	$ 4,548[1]
Center revenue	480	342
Total product revenue	6,520	4,890
Service revenue		
VIP	8,517	7,541
Billing intelligence services	905[2]	620[2]
Management service revenue (includes MID)	313	-
Sponsorship/seminar/other	630	15
Total service revenue	10,365	8,176
Total revenue	$ 16,885	$ 13,066

(1) Revenue from the sale of products is typically fixed at inception of the contract and is recognized at the point in time when shipment of the related products occurs.

(2) Revenue from maintenance and subscription contracts is typically fixed at inception of the contract and is recognized ratably over time as the services are performed and the performance obligations completed.

Changes in Contract Liabilities

The key components of changes in contract liabilities for the years ended December 31, 2021 and 2020 are as follows (in thousands):

	December 31,	
	2021	**2020**
Balance at beginning of year	$ 2,938	$ 2,948
New contracts, net of cancellations	7,978	7,531
Revenue recognized	(8,517)	(7,541)
Balance at end of year	$ 2,399	$ 2,938

Shipping Costs

Shipping costs for product deliveries to customers are expensed as incurred and totaled approximately $0.1 million for the years ended December 31, 2021 and 2020. Shipping costs for product deliveries to customers are included in cost of goods sold in the accompanying consolidated statement of operations.

NOTE 4 - PROPERTY AND EQUIPMENT, NET

As of December 31, 2021 and 2020, property and equipment consist of the following (in thousands):

	December 31, 2021	December 31, 2020
Furniture and equipment	$ 1,394	$ 936
Leasehold improvements	2,387	519
Construction in progress	212	143
Molds	75	75
Gross property and equipment	4,068	1,673
Less accumulated depreciation	(1,243)	(801)
Net Property and equipment	$ 2,825	$ 872

Leasehold improvements relate to the Vivos Institute and the two Company-owned dental centers in Colorado. Total depreciation and amortization expense was $0.4 million and $0.3 million for the years ended December 31, 2021 and 2020, respectively.

NOTE 5 – GOODWILL AND INTANGIBLE ASSETS

Goodwill

Goodwill by reporting unit consisted of the following as of December 31, 2021 and 2020 (in thousands):

	December 31,	
Reporting Unit	**2021**	**2020**
Vivos Solutions	$ 2,619	$ 2,619
Empowered Dental	52	52
Lyon Dental	172	-
Total goodwill	$ 2,843	$ 2,671

On April 14, 2021, we acquired Lyon Management and Consulting, LLC (Lyon Dental). The business acquisition allows us to expand and enhance its current medical billing practice services which are conducted through our BIS offering. The consideration transferred includes $0.2 million in cash and 25,000 warrants at a price of $8.90 per share fair valued using a Black-Scholes Model as of April 14, 2021 for a total of $0.2 million, when combined the total consideration exchanged is $0.4 million, the excess of the consideration transferred over the fair value of the acquired assets was allocated to Goodwill.

Intangible Assets

As of December 31, 2021 and 2020, identifiable intangible assets were as follows (in thousands):

	December 31, 2021	December 31, 2020
Patents and developed technology	$ 2,136	$ 1,775
Trade name	330	330
Other	27	27
Total intangible assets	2,493	2,132
Less accumulated amortization	(2,152)	(1,862)
Net intangible assets	$ 341	$ 270

Amortization expense of identifiable intangible assets was $0.3 million and $0.4 million for the years ended December 31, 2021 and 2020. The estimated future amortization of identifiable intangible assets is as follows (in thousands):

Year Ending December 31,	
2022	$ 39
2023	39
2024	39
2025	39
2026	23
Thereafter	162
Total	$ 341

NOTE 6 – OTHER FINANCIAL INFORMATION

Note Receivable

In October 2019, the Company sold its dental center in Utah to an entity controlled by the spouse of an employee for total consideration of approximately $1.2 million, including a note receivable of approximately $1.0 million. This note receivable provides for stated interest rate of 6.0%. Based on consideration of prevailing market interest rates at the time of sale and the credit risk of the purchaser, the Company recorded a discount on the note receivable of approximately $0.1 million that is being accreted to interest income over a five-year period. Interest income related to the note receivable amounted to approximately $0.1 million for each of the years ended December 31, 2021 and 2020. Due to uncertainty around collections, the note receivable was impaired as of December 31, 2021. To the extend cash is collected in the future, we will recognize income in the period cash is collected.

Accrued Expenses

Accrued expenses consist of the following (in thousands):

	December 31, 2021	December 31, 2020
Accrued payroll	$ 1,397	$ 1,025
Accrued legal and other	990	412
Lab rebate liabilities	466	300
Total accrued liabilities	$ 2,853	$ 1,737

NOTE 7 - DEBT

Summary of Debt

As of December 31, 2021 and 2020, the Company's debt consisted of the following (in thousands):

	December 31, 2021	December 31, 2020
Empowered Dental loan, due December 2020	$ -	$ 25
PPP loan maturing May 2022	1,265[(1)]	1,265[(1)]
Total debt	1,265	1,290
Less current maturities	1,265	867
Long-term debt, net of current maturities	$ -	$ 423

(1) Please see caption below for further discussion of the terms of the PPP loan.

In November 2018, the Company issued convertible debt of $25,000 as part of the consideration in an asset purchase agreement with Empowered Dental Lab, LLC. The debt was convertible into shares of the Company's common stock at a conversion rate of $7.50 per share. The interest rate on the debt was 10.0% per annum beginning July 1, 2020, and the maturity date was extended to December 31, 2020. The Company repaid this convertible debt plus interest in January 2021.

PPP Loan

On May 8, 2020, the Company received approximately $1.3 million in funding through the U.S. Small Business Administration's Payroll Protection Program (PPP) that was part of the Coronavirus Aid, Relief, and Economic Security Act signed into law in March 2020. The interest rate on the loan is 1.00% per year and matures on May 5, 2022. The Company used these funds to assist with payroll, rent and utilities. The Company has spent the funding in a manner in which it believes the entire balance of the outstanding promissory note will be eligible for forgiveness through the terms of the PPP. An application to forgive the entire amount was submitted with the lender in January 2021, as of December 31, 2021 the application was under review. On January 21, 2022 the PPP loan was forgiven by the SBA in its entirety. As a result, the Company will record other income on the forgiveness of the loan in the first quarter of 2022.

Convertible Notes

In April 2019, the Company began offering 6.0% convertible notes (the "Convertible Notes") to accredited investors in a private placement. Upon the closing of an aggregate gross cash consideration to the Company of at least $10 million (a "Qualified Financing"), the outstanding loan balance of the Convertible Notes (the "Loan Balance") shall be automatically converted into that number or principal amount of the securities of the Company issued in the Qualified Financing (the "New Securities") at a conversion price equal to (a) seventy-five percent (75%) of the price per share (or conversion price per share as the case may be) of New Securities paid by the investors in such Qualified Financing if the Qualified Financing occurs on or prior to December 31, 2019 and (b) fifty percent (50%) of the price per share (or conversion price per share as the case may be) of New Securities paid by the investors in such Qualified Financing if the Qualified Financing occurs after December 31, 2019; provided, however, that in no event for purposes of any mandatory conversion shall the Loan Balance be convertible at a price lower than $7.50 per share, which shall serve as a floor price. In any such conversion, the holders of the Convertible Notes shall be provided with all of the same rights, privileges and preferences (including contractual rights and protections such as pre-emptive rights, rights of first refusal, co-sale rights, information and registration rights) as are provided to the holders of the New Securities issued in such Qualified Financing. The Company incurred less than $0.1 million in issuance costs associated with the Convertible Notes. The maturity date of the Convertible Notes was March 31, 2020. One holder of a less than $0.1 million note elected to be paid out the principal and interest which was repaid in December 2020. During the year ended December 31, 2020, holders of $2.9 million exchanged outstanding principal and interest on the notes into Series B preferred units discussed in Note 8. Holders of $0.8 million of principal (plus $26 thousand in accrued interest) exchanged their Convertible Notes into the Company Class A common stock.

NOTE 8 – PREFERRED STOCK

The Company's Board of Directors has authority to issue up to 50,000,000 shares of Preferred Stock. Through December 31, 2020, the Board of Directors had designated 1.0 million and 1.2 million shares of Preferred Stock as Series A and Series B, respectively. Through December 31, 2020, all previously issued shares of Preferred Stock had been redeemed or converted to shares of Common Stock. As of December 31, 2021, the Board of Directors has authority to designate up to an additional 47.8 million shares of Preferred Stock in various series that provide for liquidation preferences, and voting, dividend, conversion, and redemption rights as determined at the discretion of the Board of Directors.

Further details about the terms of the Series A and Series B Preferred Stock are set forth below.

Redeemable Series A Preferred Stock

In May 2017, the Company entered into a Definitive Purchase Agreement (the "DPA") to acquire all of the licensed intellectual property, consisting primarily of patents, from its largest shareholder, current Chief Medical Officer and former majority shareholder of BioModeling. The Company's Board of Directors previously authorized the issuance of 1,000,000 shares of Series A convertible preferred stock ("Series A Preferred Stock") with a stated value of $5.00 per share. Each share was convertible at any time into one share of Class A common stock and each share of Series A Preferred Stock was also entitled to one vote. The Series A Preferred Stock was redeemable at the Company's option at any time for the stated value and at the option of the holder at 20% each year, commencing twelve months from the closing date with a limitation of $1.0 million in any twelve-month period unless otherwise authorized by the Board of Directors.

In accordance with ASC 480, the Company accounted for the Series A Preferred Stock as temporary equity. As such, the carrying value of the shares was accreted over time such that the carrying value of the shares was at least equal to the then current redemption value of the shares. The accretion was recorded as a reduction of Additional Paid-In Capital and an increase to Series A Preferred Stock. As a result of the IPO that was completed in December 2020, the Company agreed to redeem all remaining Series A Preferred Stock in December 2020 representing 700,000 shares and $3.5 million. During the year ended December 31, 2020, the Company recognized accretion of $2.3 million for the remaining redemption value. For the year ended December 31, 2020, the Company agreed to redeem 730,000 shares of the Series A Preferred Stock for a total redemption price of $3.7 million. The redemption price was paid in 2020 for a total of $2.2 million and $1.5 million was recognized as a current liability that was paid in January 2021.

Series B Preferred Stock

On January 9, 2020, the Company's Board of Directors designated 1,200,000 shares of Preferred Stock as Series B. The terms of the Series B Preferred Stock provided for par value of $0.0001 per share and an issuance price of $15.00 per share. The shares of Series B Preferred Stock did not provide the holders with rights to demand redemption, dividends, or to vote as a class with the Company's holders of Common Stock. Upon liquidation, the shares of Series B Preferred had priority over the holders of shares of Common Stock. The terms of the Series B Preferred Stock provided for mandatory conversion to shares of Common Stock upon a sale of the Company or upon completion of a qualified financing for aggregate gross cash proceeds of at least $15.0 million (referred to as an "MC Event"). Upon a MC Event, the shares of Series B Preferred automatically converted to shares of Common Stock based on a conversion price equal to 75% of the price paid by investors in a sale of the Company or a qualified financing.

The Company commenced a private placement of units (the "Series B Units") consisting of (i) one share of Series B Preferred, and (ii) one warrant to be issued for the number of shares of common stock into which the Series B Preferred stock was convertible upon a MC Event (the "Contingent Warrants"). The Contingent Warrants provided for an exercise price equal to 125% of the price of the Company's shares of Common Stock on the date of a MC Event. The Company reported no beneficial conversion on the Contingent Warrants as the warrant has a contingent beneficial conversion feature that is not calculated as a separate derivative until the contingent event has occurred. The private placement provided for the sale of units at an issuance price of $15.00 per unit. Based on the terms of the Series B Preferred, the Company classified it within permanent equity during the periods it was outstanding.

For the year ended December 31, 2020, the Company issued 163,500 Series B Units for net proceeds of approximately $2.5 million. Additionally, holders of the Convertible Notes discussed in Note 7 agreed to exchange an aggregate principal and accrued interest balance of approximately $2.9 million into 196,258 shares of Series B Preferred. Offering costs associated with this issuance of Series B Unites amounted to approximately less than $0.1 million. In December 2020, all shares of Series B Preferred Stock were converted into 1,199,195 shares of Common Stock since the IPO discussed in Note 9 triggered the MC Event. In addition, as discussed in Note 10, the MC Event resulted in the issuance of the Contingent Warrants that provide for the purchase of 1,199,195 shares of Common Stock at an exercise price of $7.50 per share.

NOTE 9 – COMMON STOCK

The Company is authorized to issue 200,000,000 shares of common stock, par value of $0.0001 per share and 50,000,000 of preferred stock, par value of $0.0001 per share. Holders of the common stock are entitled to one vote for each share held. The Company's Board of Directors may declare dividends payable to the holders of Common Stock. For the years ended December 31, 2021 and 2020, the Company completed initial public offerings of its shares of Common Stock as discussed below.

May 2021 Follow-on Offering

In May 2021, the Company completed a follow-on offering of 4.6 million shares of Common Stock at an issuance price of $6.00 per share for gross proceeds of $27.6 million. The net proceeds amounted to approximately $25.4 million after deducting an aggregate of $2.2 million for underwriting discounts and commissions and offering expenses payable by the Company.

December 2020 IPO

For the year ended December 31, 2020, the Company issued 4,025,000 shares of common stock for net proceeds of approximately $21.6 million in an initial underwritten public offering. Offering costs associated with this stock issuance were approximately $.07 million. The Company also issued 1,199,195 shares issued through the conversion of all shares of Series B Preferred Stock.

NOTE 10 – STOCK OPTIONS AND WARRANTS

Stock Options

In 2017, the Company's shareholders approved the adoption of a stock and option award plan (the "2017 Plan"), under which shares were reserved for future issuance for options, restricted stock awards and other equity awards. The 2017 Plan permits grants of equity awards to employees, directors, consultants and other independent contractors. The Company's shareholders have approved a total reserve of 1,333,333 million shares for issuance under the 2017 Plan.

In April 2019, the Company's shareholders approved the adoption of a stock and option award plan (the "2019 Plan"), under which shares were reserved for future issuance for options, restricted stock awards and other equity awards. The 2019 Plan permits grants of equity awards to employees, directors, consultants and other independent contractors. The Company's shareholders have approved a total reserve of 333,334 shares for issuance under the 2019 Plan. Consecutively, on June 18, 2020, and July 28, 2021 the Company's stockholders approved an amendment and restatement of the 2019 Plan to increase the number of shares of Common Stock available for issuance thereunder by 2,033,333 shares of Common Stock such that, after amendment and restatement of the 2019 Plan, and prior to any grants, 2,366,667 shares of Common Stock were available under the 2019 Plan.

During the years ended December 31, 2021 and 2020, the Company issued stock options to purchase 969,000 and 429,012 shares at a weighted average exercise price of $5.23 and $7.50 per share of the Company's common stock, respectively, to certain members of the Board of Directors, employees and consultants. The stock options allow the holders to purchase shares of the Company's common stock at prices between $1.50 and $7.50 per share. Options for the purchase of 220,001 and 26,667 shares of common stock expired as of December 31, 2021 and 2020, respectively. The following table summarizes all stock options as of December 31, 2021 and 2020 (shares in thousands):

	2021			2020		
	Shares	Price [1]	Term [2]	Shares	Price [1]	Term [2]
Outstanding, beginning of year	2,302	$ 4.84	1.3	1,900	$ 4.29	3.1
Grants	969	5.23		429	7.50	
Forfeited	(220)	6.25		(27)	7.50	
Exercised	(200)[3]	1.65		-	-	
Outstanding, end of year	2,851[4]	4.96	3.3	2,302[4]	4.84	1.3
Vested, end of year	1,898[5]	4.53	2.7	1,673[5]	4.10	2.5

(1) Represents the weighted average exercise price.
(2) Represents the weighted average remaining contractual term until the stock options expire.
(3) On the respective exercise dates, the aggregate intrinsic value of shares of Common Stock issued upon exercise of stock options amounted to $0.6 million.
(4) As of December 31, 2021 and 2020, the aggregate intrinsic value of stock options outstanding was $0 million and $3.1 million, respectively.
(5) As of December 31, 2021 and 2020, the aggregate intrinsic value of vested stock options was $0 million and $2.0 million, respectively.

For the years ended December 31, 2021 and 2020, the valuation assumptions for stock options granted under the 2017 Plan and the 2019 Plan were estimated on the date of grant using the BSM option-pricing model with the following weighted-average assumptions:

	2021	2020
Grant date closing price of Common Stock	$ 5.23	$ 7.50
Expected term (years)	3.5	3.2
Risk-free interest rate	0.8%	0.4%
Volatility	141%	134%
Dividend yield	0%	0%

Based on the assumptions set forth above, the weighted-average grant date fair value per share for stock options granted for the years ended December 31, 2021 and 2020 was $4.96 and $4.84, respectively.

For the years ended December 31, 2021 and 2020, the Company recognized approximately $2.7 million and $2.2 million, respectively, of share-based compensation expense relating to the vesting of stock options. Unrecognized expense relating to these awards as of December 31, 2021 was approximately $4.8 million, which will be recognized over the weighted average remaining term of 2.9 years as of December 31, 2021.

Warrants

The following table sets forth warrant activity for the years ended December 31, 2021 and 2020 (shares in thousands):

	2021			2020		
	Shares	**Price [1]**	**Term [2]**	**Shares**	**Price [1]**	**Term [2]**
Outstanding, beginning of year	1,960	$ 7.44	3.5	33	$ 1.50	1.5
Grants of warrants:						
Underwriter pursuant to IPOs	276[3]	7.50		403[4]	7.50	
Consultants for services	95[5]	7.50		-	-	
Acquisition of assets	200[6]	7.50		-	-	
Business combination	25[7]	8.90		-	-	
Contingent warrants	-	-		1,199[8]	$ 7.50	
Settlement warrants	-	-		325[9]	7.50	
Outstanding, end of year	2,556[10]	7.44	2.6	1,960[10]	7.44	3.5
Vested, end of year	2,311[11]	7.42	2.2	1,960[11]	7.40	3.5

(1) Represents the weighted average exercise price.

(2) Represents the weighted average remaining contractual term until the warrants expire.

(3) In connection with its registered underwritten follow-on offering in May 2021, the Company granted warrants to the underwriter that provide for the purchase of 276,000 shares of Common Stock at an exercise price of $7.50 per share with a fair value of approximately $1.5 million. These warrants became exercisable in November 2021 and expire in May 2026.

(4) In connection with the IPO in December 2020, the Company granted warrants to the underwriter that provide for the purchase of 402,500 shares of common stock at an exercise price of $7.50 per share. These warrants became exercisable in June 2021 and expire in December 2025.

(5) In March 2021, the Company granted warrants to consultants in exchange for services. Warrants issued in March 2021 provide for the purchase of an aggregate of 95,000 shares of Common Stock and are exercisable at $7.50 per share. The aggregate fair value of the March warrants amounted to $0.2 million which is being recognized over the period that the services are provided. For the year ended December 31, 2021, the Company recognized expense of $0.2 million.

(6) In March 2021, the Company granted warrants in connection with the acquisition of certain assets from MyoCorrect, LLC ("MyoCorrect") that provide for the purchase of up to 200,000 shares of Common Stock through March 2026. The aggregate fair value of these warrants amounted to $0.1 million which is being recognized over the vesting period. Warrants to purchase 25,000 shares of Common Stock vested in March 2021 and the remainder vest upon the achievement of pre-determined performance metrics related to the utilization of MyoCorrect, with a five-year term.

(7) In April, 2021, the Company granted warrants in connection with a business combination. Warrants granted in April 2021 provide for the purchase of an aggregate of 25,000 shares of Common Stock and are exercisable at $8.90 per share. The aggregate fair value of the April warrants amounted to $0.2 million which is being recognized over the period that the services are provided. For the year ended December 31, 2021, the Company recognized expense of $0.2 million.

(8) Pursuant to the terms of the Series B Units and in connection with the IPO which qualified as a MC Event, approximately 1,199,000 Contingent Warrants were issued at an exercise price equal to 125% of the price of the Company's shares of common stock on the date of an MC event, or $7.50 per share based on the IPO price of $6.00 per share.

(9) On October 22, 2020, two minority stockholders initiated a derivative demand which resulted in a settlement and release agreement that was entered into on November 6, 2020. Pursuant to the settlement, the Company issued warrants to purchase an aggregate of 325,000 shares of common stock (the "Settlement Warrants"). The Settlement Warrants are exercisable on a cash only basis at an exercise price of $7.50 per share, are exercisable beginning on June 15, 2021, and expire on May 6, 2024.

(10) As of December 31, 2021 and 2020, the aggregate intrinsic value of warrants outstanding was $0.

(11) As of December 31, 2021 and 2020, the aggregate intrinsic value of vested warrants was $0.

For the years ended December 31, 2021 and 2020, the valuation assumptions for warrants were estimated on the measurement date using the BSM option-pricing model with the following weighted-average assumptions:

	2021	2020
Measurement date closing price of Common Stock [1]	$ 7.44	$ 7.50
Contractual term (years) [2]	2.6	3.5
Risk-free interest rate	0.3%	0.3%
Volatility	138%	139%
Dividend yield	0%	0%

(1) Weighted average grant price.

(2) The valuation of warrants is based on the contractual term of the warrant rather than the expected term.

NOTE 11 - RELATED PARTY TRANSACTIONS

The Company was a party to a management agreement with Upeva, Inc., a company for which the Company's prior Secretary and one of the Company's former board members serves as chief executive officer. In return for various legal and other consulting services, the Company paid Upeva a monthly fee of $10,000. This agreement terminated on April 30, 2020. As of December 31, 2020, the Company owed Upeva, Inc. approximately $10,000. The former Secretary and director is the beneficial owner of 254,902 common shares of the Company through Spire Family Holdings, L.P. Additionally, the former Secretary and director is the beneficial owner of 254,902 common shares of the Company through Spire Family Holdings, L.P. The payment was made early 2021, no outstanding fees are due.

During the year ended December 31, 2020, one of the Company's former directors who held $0.2 million in 2019 Notes exchanged her outstanding notes for Series B preferred units, which converted into 45,252 common shares.

During 2020, one of the Company's Directors and holder of the Company's Series A preferred stock, exercised his right to redeem 730,000 shares of the Series A preferred stock for $5.00 per share for a total of $3.7 million. Per the director's request, $2 million was paid in December 2020, and the rest was paid in full in January 2021.

In July 2020, two of the directors voluntarily entered into separation agreements with our company. Such agreements contained customary releases, confidentiality and non-disparagement provisions. As consideration for the entering the separation agreements, each director received an equity grant in the amount 16,667 shares and the ability to retain and exercise their previously granted and vested options, and the Company also committed to providing continued indemnification obligations consistent with organizational documents and to retain director's and officer's insurance for a period of twenty-four months in connection with two of the directors' prior service on the board.

In August 2020, the Company also entered into a Separation Agreement with another director pursuant to which the Company is required to purchase from the director and her affiliated entities 13,575 shares of Series B Preferred Stock and warrants to purchase common stock and 16,667 shares of common stock held for an aggregate purchase price of $0.3 million. If the Company was unable to close a qualified financing, as defined in the agreement of at least $3 million of equity or equity-linked securities by September 15, 2020 (as was extended up to October 28, 2020), a modified consideration would include 16,667 shares of unrestricted, fully vested common stock, a grant of stock options to purchase 33,334 shares of common stock at a price of $7.50 that will be fully vested and exercisable and $22 thousand in cash. The Company recorded general and administrative expense and accrued expenses of approximately $0.3 million for cash and equity issuances with this settlement. In November 2020, the Company granted this former director 16,667 shares of unrestricted, fully vested common stock, a grant of stock options to purchase 33,334 shares of common stock at a price of $7.50 that will be fully vested and exercisable and paid $47 thousand in cash (including $25 thousand for legal fees) to settle terms outlined in her separation agreement.

On October 22, 2020, two minority stockholders of the Company, Lazarus Asset Management, LLC and a former director of the Company (who we refer to as the Demanding Stockholders), sent a derivative demand to the Company through counsel asking the board of directors to review and investigate certain recent actions taken by the board of directors, or members thereof, and senior management including (i) pursuit of the initial public offering described in the Company's filing on Form S-1, (ii) the board of directors' previous rejection (on two occasions) of a "reverse merger" transaction proposal made by Lazarus Asset Management, LLC, (iii) purported mismanagement of corporate assets, and (iv) various matters related to stock sales and other matters. After discussions with the Demanding Stockholders and their counsel, the Company ascertained that the Demanding Stockholders were acting for themselves and on behalf of an additional group of minority shareholders, (we refer to the Demanding Stockholders and all such other minority shareholders they acted on behalf of collectively as the Stockholder Group).

While the Company believes that the assertions of the Demanding Stockholders lacked any merit in fact and in law, rather than expending resources investigating or litigating the claims of the Demanding Stockholders, and in order to proceed with the Company's initial public offering, on November 6, 2020, without admitting or denying any claims asserted by the Demanding Stockholders, the Company entered into a Settlement and Release Agreement with each member of the Stockholder Group (which the Company refers to as the Settlement and Release Agreement). Pursuant to the Settlement and Release Agreement, all claims of the Demanding Stockholders were withdrawn with prejudice, and the Company and the Stockholder Group provided each other with full releases of any claims. In consideration of such withdrawal and releases, the members of the Stockholder Group have received: (i) an aggregate of 300,000 shares of Company common stock and (ii) warrants to purchase an aggregate of 325,000 shares of common stock (see Note 9). Such warrants (x) will be exercisable on a cash only basis at a strike price of 125% of the public offering price per share in a Company qualified public offering of more than $10 million, (y) will be exercisable for a period of 36 months, beginning six months after the consummation of a qualified public offering and ending on the forty-second month anniversary of a Company qualified public offering. Finally, the Settlement and Release Agreement contains customary representations, warranties and covenants, including relating to confidentiality and non-disparagement, and the Company agreed to reimburse the Demanding Stockholders for up to $50 thousand of their legal fees associated with the demand letter the Company received on October 22, 2020 from them.

For the year ended December 31, 2021 and 2020, options for the purchase of 539,000 and 429,012 shares, respectively, of the Company's common stock were granted to the Company's directors, officers, employees and consultants.

NOTE 12 - INCOME TAXES

For the years ended December 31, 2021 and 2020, the domestic and foreign components of loss before income taxes consist of the following (in thousands):

	2021	2020
Domestic	$ (20,307)	$ (12,072)
International	19	15
Loss before income taxes	$ (20,288)	$ (12,057)

For the years ended December 31, 2021 and 2020, income tax expense (benefit) consists of the following (in thousands):

	2021	2020
Current income tax benefit (expense):		
Federal	$ -	$ -
States	-	-
Total current income tax benefit (expense)	-	-
Deferred income tax benefit (expense):		
Federal	-	-
States	-	-
Total deferred income tax benefit (expense)	-	-
Total income tax expense (benefit)	$ -	$ -

For the years ended December 31, 2021 and 2020, income tax benefit differed from amounts that would result from applying the U.S. statutory income tax rate of 21.0% to the Company's loss before income taxes as follows (in thousands):

	2021	2020
Income tax benefit computed at federal statutory rate	$ (4,261)	$ (2,507)
Permanent differences	109	1,622
State tax expenses	(502)	(181)
Prior year adjustment to state NOL	(275)	
Change in valuation allowance	4,929	1,066
Total income tax benefit	$ -	$ -

As of December 31, 2021 and 2020, the principal components of deferred tax assets and liabilities were as follows (in thousands):

	2021	2020
Deferred tax assets:		
Net operating loss carryforwards	9,150	5,105
Stock based compensation	1,005	609
Other	699	336
Total deferred tax assets before valuation allowance	10,854	6,050
Valuation allowance	(10,766)	(5,837)
Total deferred income tax assets after valuation allowance	88	213
Deferred tax liabilities:		
Property, equipment and intangibles	(88)	(213)
Other	-	-
Total deferred income tax liabilities	(88)	(213)
Net deferred tax assets and liabilities	$ -	$ -

Management assesses the available positive and negative evidence to estimate if sufficient future taxable income will be generated to use the existing deferred tax assets. A significant piece of objective negative evidence evaluated was the cumulative loss incurred since inception. Such objective evidence limits the ability to consider other subjective evidence such as our projections for future growth. On the basis of this evaluation, as of December 31, 2021, a valuation allowance of $10.8 million has been recorded to record the deferred tax asset that is more likely than not to be realized. The net change during the year in the total valuation allowance is an increase of $4.9 million.

The Company has federal net operating loss carry forwards of $38.4 million. The Company also has various state net operating loss carry forwards. The determination of the state net operating loss carry forwards is dependent upon the apportionment percentages and state laws that can change from year to year and impact the amount of such carry forwards. If federal net operating loss carry forwards are not utilized, approximately $3.3 million will begin to expire in 2036. As of December 31, 2021, the remaining federal net operating losses of $35.1 million have no expiration dates.

Federal and state laws impose substantial restrictions on the utilization of net operating loss ("NOL") carryforwards in the event of an ownership change for income tax purposes, as defined in Section 382 of the Internal Revenue Code ("IRC"). Pursuant to IRC Section 382, annual use of the Company's NOL carryforwards may be limited in the event a cumulative change in ownership of more than 50% occurs within a three-year period. The Company has not completed an IRC Section 382 analysis regarding the limitation of NOL carryforwards. However, it is possible that past ownership changes will result in the inability to utilize a significant portion of the Company's NOL carryforward that was generated prior to any change of control. The Company's ability to use its remaining NOL carryforwards may be further limited if the Company experiences an IRC Section 382 ownership change in connection with future changes in the Company's stock ownership.

Management does not believe that there are significant uncertain tax positions related to the 2021 and 2020 taxable periods. There are no interest and penalties related to uncertain tax positions for the years ended December 31, 2021 and 2020.

The Company files income tax returns in the United States federal and various state jurisdictions. The Company is no longer subject to income tax examinations for federal income taxes before 2016 or for states before 2015. Net operating loss carryforwards are subject to examination in the year they are utilized regardless of whether the tax year in which they are generated has been closed by statute. The amount subject to disallowance is limited to the NOL utilized. Accordingly, the Company may be subject to examination for prior NOL's generated as such NOL's are utilized. As of December 31, 2021, the Company has filed all appropriate foreign operation tax returns.

NOTE 13 – COMMITMENTS AND CONTINGENCIES

COVID-19 Pandemic

In December 2019, a novel strain of coronavirus known as COVID-19 was reported to have surfaced in China, and by March 2020 the spread of the virus resulted in a world-wide pandemic. By March 2020, the U.S. economy had been largely shut down by mass quarantines and government mandated stay-in-place orders (the "Orders") to halt the spread of the virus. Many of these Orders have been relaxed or lifted in jurisdictions where large portions of the population have been vaccinated, but there is considerable uncertainty about whether the Orders will need to be reinstated due to the ongoing spread of new variants of COVID-19. A significant portion of the worldwide population remains unvaccinated, and uncertainty also exists about whether existing vaccines will be effective as new variants of COVID-19 emerge. Accordingly, the overall impact of COVID-19 continues to have an adverse impact on global business activities.

Many of the Company's VIPs and potential VIPs closed their offices during periods of 2020 as a result of COVID-19, although some remained open to specifically provide patients with Company products as Company appliances and VIPs were deemed an essential business for health considerations in many jurisdictions. In the face of the pandemic and the results potential for revenue reduction, Company management worked diligently to reduce expenses and maintain revenues during 2020. While revenue growth flattened in March and April 2020, expenses were reduced and the Company aggressively expanded its network of healthcare providers familiar with its products by offering online continuing education courses which introduced many in the medical and dental communities to the Company's product line. As businesses continued to reopen through 2021, the impact of COVID-19 on the Company began to diminish, although the Company is closely monitoring the potential impact of COVID-19 variants on its business. Of note, second half of the year, many of the Company's Canadian VIPs have not traveled to the US for training in light of travel restrictions. As of August 9, 2021, the Government of Canada imposed further restrictions on unvaccinated travelers, which has caused delays with some of the Company's Canadian VIPs receiving required training and commencing Vivos Method cases.

Fourth quarter 2021 revenue growth was impacted by lower VIP enrollments due largely to the COVID-19 Delta and Omicron variant resurgences. The Company achieved sales growth despite seeing significant headwinds throughout our core customer base, mostly driven by such COVID-19 variant resurgences in the middle and latter part of the year. In December 2021, the American Dental Association reported that just 60% of dental practices were open and operating with business as usual. Another industry source reported 92% of dental practices were struggling to hire or replace hygienists, and 77% reported difficulty hiring front desk positions. These challenges across the dental community have impacted both doctor enrollments and patient case starts, as replacement dental personnel must be trained in The Vivos Method.

The world-wide response to the pandemic resulted in a significant downturn in economic activity and there is no assurance that government stimulus programs will successfully restore the economy to the levels that existed before the pandemic. In addition, worldwide supply chain constraints and inflation have emerged as new barriers to long-term economic recovery. If an economic recession or depression is sustained, it could have a material adverse effect on the Company's business as demand for its products could decrease. While the current disruption to the Company's business is expected to be temporary, the long-term financial impact on the Company's business cannot be reasonably estimated at this time.

Litigation Settlement

In October 2020, the Company received a derivative demand from certain stockholders (the "Derivative Action") asking the Board of Directors to review and investigate certain recent actions taken on behalf of the Company. Upon further investigation, the Company determined that the assertions of the Derivative Action lacked merit in fact and in law. However, rather than expending resources investigating or litigating the claims set forth in the Derivative Action, and in order to proceed with the Company's December 2020 IPO discussed in Note 9, the Company entered into a Settlement and Release Agreement in November 2020 without admitting or denying any of the claims that were asserted. Pursuant to the Settlement and Release Agreement, all claims under the Derivative Action were withdrawn with prejudice, and the parties provided each other with full releases of any claims.

In consideration of such withdrawal and releases, the parties to the Derivative Action received (i) an aggregate of 300,000 shares of Common Stock with a fair value of $1.8 million, (ii) warrants to purchase an aggregate of 325,000 shares of Common Stock with an estimated fair value $1.5 million, and (iii) reimbursement of up to $50 thousand for legal fees incurred. The warrants to purchase 325,000 shares of Common Stock are exercisable by paying the exercise price of $7.50 per share in cash, and are exercisable for the period from June 2021 until June 2024 when they expire if not previously exercised. The total costs to settle the Derivative Action amounted to $3.3 million, which is included in the accompanying statement of operations for the year ended December 31, 2020.

Operating Leases

The Company leases office properties under various lease terms. Rent expense, including real estate taxes and related costs, for the years ended December 31, 2021 and 2020 aggregated approximately $0.6 million and $0.5 million, respectively. In connection with some of the Company's leases, lease incentives were granted. Deferred lease incentives are being amortized on a straight-line basis over the term of the lease.

Future rental payments over the term of the Company's leases are as follows (in thousands):

Years Ending December 31,		
2022	$	491
2023		479
2024		495
2025		440
2026		345
Thereafter		555
Total operating lease payments	$	2,805

Employment Agreements

During 2020, the Company entered into new employment agreements with its chief executive officer, chief medical officer and chief financial officer. The agreements include incentive compensation in the form of cash bonuses and stock options. The employment agreements require the continuation of salary and benefits for up to two years in the event the employee is terminated without cause.

Regulatory status

In September 2017, BioModeling was the subject of a routine FDA audit. The audit resulted in certain findings that BioModeling was required to remediate. On September 27, 2017, BioModeling believed that it had filed its response letter to the audit findings with the FDA. In January 2018, BioModeling received notice that the FDA had posted a Warning Letter on its website alleging failure by BioModeling to reply in a timely manner to the September 2017 audit findings. The Company and BioModeling immediately contacted the FDA in January 2018 and resubmitted the September 27, 2017 audit response letter. In April 2018, the FDA completed a second audit of BioModeling which focused on the September 2017 response letter and the Warning Letter. The Company believes that this issue has been satisfactorily resolved although no definitive statement to that effect has been made by the FDA.

401(k) Plan

The Company has a defined contribution employee benefit plan under section 401(k) of the Code (the "401(k) Plan"). The 401(k) Plan covers all eligible U.S. employees that are entitled to participate at the beginning of the first full quarter following commencement of employment. The Company matches the entire amount of the employee contributions up to 3% of the participating employee's compensation, and then 50% of employee contributions between 4% and 5% of the participating employee's compensation. These matching contributions vest for 100% when the matching contributions are made. Total contributions to the 401(k) Plan amounted to $0.4 million and $0.3 million for the years ended December 31, 2021 and 2020, respectively.

NOTE 14 – NET LOSS PER SHARE OF COMMON STOCK

Basic and diluted net loss per share of Common Stock ("EPS") is computed by dividing (i) net loss, as adjusted for beneficial conversion features and accretion related to Preferred Stock (the "Numerator"), by (ii) the weighted average number of common shares outstanding during the period (the "Denominator").

The calculation of diluted EPS is also required to include the dilutive effect, if any, of stock options, unvested restricted stock awards, convertible debt and Preferred Stock, and other Common Stock equivalents computed using the treasury stock method, in order to compute the weighted average number of shares outstanding. For the years ended December 31, 2021 and 2020, all Common Stock equivalents were antidilutive.

Presented below are the calculations of the Numerators and the Denominators for basic and diluted EPS (dollars in thousands, except per share amounts):

	2021	2020
Calculation of Numerator:		
Net loss	$ (20,288)	(12,057)
Warrant beneficial conversion feature	-	(3,598)[1]
Accretion of Series A Preferred Stock redemption amount	-	(2,333)[2]
Loss applicable to common stockholders	$ (20,288)	$ (17,988)
Calculation of Denominator:		
Weighted average number of shares of Common Stock outstanding	21,233	12,869
Net loss per share of Common Stock (basic and diluted)	$ (0.96)	$ (1.40)

(1) Represents the beneficial conversion feature related to warrants issued in settlement as discussed in Note 9.
(2) Represents accretion of the Series A Preferred Stock redemption premium discussed in Note 8.

The holder of the Series A Preferred Stock discussed in Note 8 was entitled to participate in Common Stock dividends, if and when declared, on a one-to-one per-share basis. Accordingly, in any periods in which the Company has net income, earnings per share was required to be computed using the two-class method whereby the pro rata dividends distributable to the holder of Series A Preferred Stock would have been deducted from earnings applicable to common stockholders, regardless of whether a dividend was declared for such undistributed earnings. For the years ended December 31, 2021 and 2020, the Company incurred a net loss and, accordingly, there were no undistributed earnings to allocate under the two-class method.

As of December 31, 2021, the following potential Common Stock equivalents were excluded from the computation of diluted net loss per share of Common Stock since the impact of inclusion was antidilutive (in thousands):

	2021	2020
Common stock warrants	2,556	1,960
Common stock options	2,851	2,302
Total	5,407	4,262

NOTE 15 - FINANCIAL INSTRUMENTS AND SIGNIFICANT CONCENTRATIONS

Fair Value Measurements

Fair value is defined as the price that would be received upon sale of an asset or paid to transfer a liability in an orderly transaction between market participants on the measurement date. When determining fair value, the Company considers the principal or most advantageous market in which it transacts and considers assumptions that market participants would use when pricing the asset or liability. The Company applies the following fair value hierarchy, which prioritizes the inputs used to measure fair value into three levels and bases the categorization within the hierarchy upon the lowest level of input that is available and significant to the measurement of fair value:

Level 1—Quoted prices in active markets for identical assets or liabilities accessible to the reporting entity at the measurement date

Level 2—Other than quoted prices included in Level 1 that are observable for the asset and liability, either directly or indirectly through market collaboration, for substantially the full term of the asset or liability

Level 3—Unobservable inputs for the asset or liability used to measure fair value to the extent that observable inputs are not available, thereby allowing for situations in which there is little, if any market activity for the asset or liability at measurement date

As of December 31, 2021 and 2020, the fair value of the Company's cash and cash equivalents, accounts receivable, accounts payable, and accrued liabilities approximated their carrying values due to the short-term nature of these instruments. Due to the U.S. government guarantee and the otherwise unique terms of the PPP Loan discussed in Note 7, it was not possible to determine fair value of this debt instrument.

Recurring Fair Value Measurements

For the years ended December 31, 2021 and 2020, the Company did not have any recurring measurements for the fair value of assets and liabilities.

The Company's policy is to recognize asset or liability transfers among Level 1, Level 2 and Level 3 as of the actual date of the events or change in circumstances that caused the transfer. During the years ended December 31, 2021 and 2020, the Company had no transfers of its assets or liabilities between levels of the fair value hierarchy.

Significant Concentrations

Financial instruments that subject the Company to concentrations of credit risk consist primarily of cash, cash equivalents, restricted cash, and accounts receivable. The Company maintains its cash, cash equivalents and restricted cash at high-quality financial institutions. Cash deposits, including those held in foreign branches of global banks, may exceed the amount of insurance provided on such deposits. As of December 31, 2021, the Company had cash and cash equivalents with two financial institutions in the United States with an aggregate balance of $24.0 million. As of December 31, 2020, the Company had cash and cash equivalents with two financial institutions in the United States with an aggregate balance of $18.2 million. The Company has never experienced any losses related to its investments in cash, cash equivalents and restricted cash.

Generally, credit risk with respect to accounts receivable is diversified due to the number of entities comprising the Company's customer base and their dispersion across different geographies and industries. The Company performs ongoing credit evaluations on certain customers and generally does not require collateral on accounts receivable. The Company maintains reserves for potential bad debts.

NOTE 16 - SUBSEQUENT EVENTS

On February 7, 2022 the Company filed a Form S-3 with the Securities and Exchange Commission, or SEC, utilizing a "shelf" registration process. Under this shelf registration process, the Company may offer and sell, either individually or in combination, in one or more offerings, any of the securities described within the Form S-3, for total gross proceeds of up to $75 million.

On February 25, 2022 the Company issued 290,000 stock options to certain employees and officers with an exercise price of $3.27 per share, one-fifth vested on the date of grant, and one-fifth vests annually through February 25, 2027. Additionally, the Company issued warrants to purchase 80,000 shares of the Company's common stock to certain consultants for sales consulting services with an exercise price of $3.27 per share, vesting monthly over one year term of the agreement.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e)) are designed to ensure that information required to be disclosed by us in reports we file or submit under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported within the appropriate time periods, and that such information is accumulated and communicated to our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely discussions regarding required disclosure. We, under the supervisions of and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, have evaluated the effectiveness of our disclosure controls and procedures. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that the design and operation of our disclosure controls and procedures were not effective because of material weakness in our internal control over financial reporting as of December 31, 2021. The material weakness is further described below.

Material Weakness in Internal Control Over Financial Reporting

In connection with the audit of our consolidated financial statements for the year ended December 31, 2021 and 2020, 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, 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. For the year ended December 31, 2021, the material weakness 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 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* Nonetheless, we have concluded that this material weakness does not require a restatement of or change in our consolidated financial statements for any prior interim period. We also developed a remediation plan for this material weakness which is described below.

Remediation of Material Weakness

We are committed to maintaining a strong internal control environment and implementing measures designed to help ensure that significant deficiencies contributing to the material weakness are remediated as soon as possible. We believe we have made progress towards remediation and continue to implement our remediation plan for the previously reported and current material weakness in internal control over financial reporting, which includes steps to increase dedicated personnel, improve reporting processes, design, and implement new controls, and enhance related supporting technology. We will consider the material weakness remediated after the applicable controls operate for a sufficient period of time, and management has concluded, through testing, that the controls are operating effectively.

Management's Report on Internal Control over Financial Reporting

This Annual Report on Form 10-K does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of our independent registered public accounting firm due to a transition period established by rules of the SEC for newly public companies.

Changes in Internal Control over Financial Reporting

Due to the identification of the material weakness described above, we continue to seek to strengthen our internal control structure by adding accounting staff, adding additional levels of review, adding accounting technical support, and implementation of a new enterprise resource planning system. Except as described herein, we made no other changes in internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act, during the year ended December 31, 2021 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not Applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Directors and Executive Officers

The following table sets forth the names, positions and ages of our directors and executive officers as of March 31, 2022. Our directors are elected by our stockholders at the annual meeting of the stockholders and have been elected via written consent of a majority of stockholders, and serve until the next annual meeting of the stockholders or, in absence of such annual meeting, until their successors are elected and qualified. Officers are elected by our board of directors and their terms of office are at the discretion of our board, subject to applicable employment agreements.

Name	Age	Positions Held	Initial Term of Office
R. Kirk Huntsman	64	Co-founder, Chairman of the Board and Chief Executive Officer	September 2016
Bradford Amman	60	Chief Financial Officer, Secretary	October 2018
Ralph E. Green	82	Director	June 2020
Anja Krammer	54	Director	June 2020
Mark F. Lindsay	58	Director	June 2020
Leonard J. Sokolow	65	Director	June 2020
Matthew Thompson	60	Director	June 2020

The biographical information concerning the directors and executive officers listed above is set forth below.

Executive Officers

R. Kirk Huntsman is a co-founder of our company and has served as our Chief Executive Officer and a director since September 2016. In June 2020, he was elected Chairman of the Board by our board of directors. In 1995, he founded Dental One (now Dental One Partners), which, as President and Chief Executive Officer he grew to become one of the leading DSOs (dental service organizations) in the country, with over 165 practices in 15 states. After a successful sale of Dental One to MSD Capital in 2008 and subsequent merger in 2009 with Dental Care Partners, Mr. Huntsman was appointed in 2010 as Chief Executive Officer of ReachOut Healthcare America, a Morgan Stanley Private Equity portfolio company. In 2012, he founded Xenith Practices, LLC, a DSO focused on rolling up larger independent general dental offices, which were sold in 2015. From January 2014 to September 2015, Mr. Huntsman founded and served as the Chief Executive Officer of Ortho Ventures, LLC, a U.S. distributor of certain pediatric oral appliances with applications for pediatric sleep disordered breathing. Since November 2015, he has served as the Chief Executive Officer of First Vivos, Inc., which is now our wholly owned subsidiary. He was also a founding member of the Dental Group Practice Association (DGPA), now known as the Association of Dental Support Organizations (ADSO). He is the father of Todd Huntsman, Sr. Vice President, Product and Technology. He holds a BS degree in finance from Brigham Young University

Bradford Amman has served as our Chief Financial Officer since October 2018. From January 2017 to October 2018, Mr. Amman served as the Chief Financial Officer and Chief Operations Officer of InLight Medical, a manufacturer and distributor of medical devices cleared by the FDA for increased circulation and reduced pain. Prior to InLight, from 2010 to 2017, he served as CereScan Corp.'s Chief Financial Officer. CereScan specializes in state-of-the-art functional brain imaging, utilizing a patented process, the latest generation functional imaging SPECT and PET cameras and the industry's leading brain imaging software to assist in the diagnosis of a magnitude of brain-related conditions and disorders. Mr. Amman served as Chief Financial Officer of LifeVantage Corporation from 2006 to 2010, including during its initial public offering. Mr. Amman holds a Master of Business Administration from the University of Notre Dame and a BS in Accounting from the University of Denver.

Directors

Ralph E. Green, DDS, MBA joined our board of directors in June 2020. He has devoted more than 35 years to senior level executive positions. Since 2003, Dr. Green has served as President and CEO of his proprietary dental practice. From 2003 to 2017 he served as Vice President of Clinical Affairs for ReachOut Healthcare America, a Morgan Stanley Private Equity company focused on Arizona's underserved children's population. From1997 through 2002, Dr. Green was President of Zila Pharmaceuticals Inc. where he was engaged in clinical trials, patent development and regulatory approval submissions. Dr. Green has done extensive research on bone growth and oral cancer. In the mid-1980's, Bofors Nobel-Pharma selected Dr. Green to establish the Swedish Branemark Dental Implant in America, now known as Nobel Biocare, the global leader in dental implants with several billions in sales. In 1987, Dr. Green discovered and patented a method of activating the titanium implant surface to enhance its success rate. He started his own titanium implant company, OTC America, which was acquired after 18 months by Collagen Corporation, where he served as Senior Vice President. Following his tenure at Collagen, he started his own consulting firm, Biofusion Technology. He also served as Assistant Professor in the Tufts University School of Medicine and School of Dental Medicine in the 1970's and 1980's. Dr. Green has served as President-elect and director of the Dental Manufacturers of America. He was honored as a fellow in the Academy of International Dentistry in Nice, France. Dr. Green holds a DDS from the University of Iowa, an MBA from Boston University and a BA in Biology from Graceland University.

Anja Krammer joined our board of directors in June 2020. In early 2020, Ms. Krammer was appointed as the Chief Executive Officer of Turn Biotechnologies, a development stage company focused on reversing aging and age-related diseases. From 2013 through 2018, she co-founded, served as President, Secretary and a director of BioPharmX, a specialty pharmaceutical company where she led the initial public offering onto the New York Stock Exchange in 2015. Ms. Krammer served as Principal/Founder of MBI, Inc., a management consulting firm beginning in January 1998. While at MBI, Inc., Ms. Krammer also served as Vice President Global Marketing from April 2006 to August 2008 for Reliant Technologies, a venture-backed startup in aesthetic medicine. From April 2004 to April 2006, Ms. Krammer served as Sr. Director of Strategic Marketing for Medtronic Corporation. From December 2000 to September 2001, Ms. Krammer was Vice President, Solutions Marketing for Getronics Corporation, a global IT services company. From April 1999 to December 2000, Ms. Krammer served as Vice President, Indirect Channel Sales and Worldwide Industry Partnership Marketing in the Itronix Division of Acterna Corporation, an optical communications company. Ms. Krammer's other prior roles include serving as Director of Worldwide Marketing and Communications for Tektronix Corporation in its Color Printing and Imaging Division from October 1997 to April 1999. From October 1995 to October 1997, Ms. Krammer was Director of Worldwide Sales and Marketing with KeyTronic Corporation, a computer equipment manufacturer. Ms. Krammer holds a BAIS degree with a focus on Marketing/Management from the University of South Carolina and an International Trade Certificate from the University of Paris—Sorbonne.

Mark F. Lindsay joined our board of directors in June 2020. Since 2008, he has served as a consultant and the director of the healthcare and pharmaceuticals practices group with the Livingston Group. From February 2001 through September 2008, Mr. Lindsay was with UnitedHealth Group, one of the world's largest healthcare companies, where he held a number of senior positions including President of the AARP Pharmacy Services Division and Vice President of Public Communications and Strategy. In 2008, he served on President Obama's transition team. From May 1996 through January 2001, Mr. Lindsay served in President Clinton's White House as Assistant to the President for the Office of Management and Administration. His areas of responsibility included the White House Military Office, which managed Air Force One; The White House Communications Agency; the Medical Unit and Camp David; running the White House Operations; and the Executive Office of the President's Office of Administration, which was responsible for finance, information systems, human resources, legal/appropriations and security. Mr. Lindsay's office was responsible for the logistics of all domestic and international Presidential travel and special air missions. President Clinton selected Mr. Lindsay to be the operational lead for the White House's 2001 transition preparation and execution. From 1994 through 1997, Mr. Lindsay served as senior legislative aid and counsel to Congressman Louis Stokes (D-OH). He worked closely with Democrats and the Congressional Black Caucus on a number of business and economic issues. He was also a member of Senator Hillary Clinton's Minnesota Finance Committee for her 2008 Presidential campaign. Mr. Lindsay holds a graduate degree from Macalester College in St. Paul, Minnesota; a Juris Doctorate from Case Western Reserve University School of Law; a master's degree in international Affairs from Georgetown University; and a graduate degree from the Advanced Management program at the University of Pennsylvania's Wharton Business School. He is a member of the District of Columbia Bar.

Leonard J. Sokolow, joined our board of directors in June 2020. Since 2015, Mr. Sokolow has been Chief Executive Officer and President of Newbridge Financial, Inc., a financial services holding company and Chairman of Newbridge Securities Corporation, its full service broker-dealer. From 2008 through 2012, he served as President and Vice Chairman of National Holdings Corporation, a publicly traded financial services company. From November 1999 until January 2008, Mr. Sokolow was Chief Executive Officer and President, and a member of the Board of Directors, of vFinance Inc., a publicly traded financial services company, which he cofounded. Mr. Sokolow was the Chairman of the Board of Directors and Chief Executive Officer of vFinance Inc. from January 2007 until July 2008, when it merged into National Holdings Corporation, a publicly traded financial services company. Mr. Sokolow was founder, chairman and chief executive officer of the Americas Growth Fund Inc., a closed-end 1940 Act management investment company, from 1994 to 1998. From 1988 until 1993, Mr. Sokolow was an Executive Vice President and the General Counsel of Applica Inc., a publicly traded appliance marketing and distribution company. From 1982 until 1988, Mr. Sokolow practiced corporate, securities and tax law and was one of the founding attorneys and a partner of an international boutique law firm. From 1980 until 1982, he worked as a Certified Public Accountant for Ernst & Young and KPMG Peat Marwick. Since June 2006, Mr. Sokolow has served on the Board of Directors of Consolidated Water Company Ltd. (NASDAQ: CWCO) and as Chairman of its Audit Committee; as well as a member of its Nominations and Corporate Governance Committee since 2011. Since January 2016 Mr. Sokolow has served as a member of the Board of Directors of SQL Technologies Corp., d/b/a Sky Technologies (NASDAQ: SKYX) and Chairman of its Audit Committee from January 2016 through February 2022 and, since September 2016, Chairman of its Corporate Development Committee. Since December 2021, Mr. Sokolow has served as a member of the Board of Directors of Agrify Corporation (NASDAQ: AGFY), where he currently serves as a member of the Audit Committee and the Compensation Committee. The Audit Committee of Vivos has determined that Mr. Sokolow meets the statutory requirements to be identified as the audit committee financial expert.

Matthew Thompson, M.D. joined our board of directors in June 2020. Since December 2016, Dr. Thompson has served as Chief Medical Officer of Endologix LLC. Dr. Thompson is an Adjunctive Professor at Stanford School of Medicine (since 2017) and contract surgeon and Visiting Professor at Cleveland Clinic Lerner College of Medicine of Case Western Reserve University (since 2020). Prior to joining Endologix, Dr. Thompson served as Professor of Vascular Surgery at St. George's University of London and St George's Vascular Institute (2002-2016). Dr. Thompson's awards include a Hunterian Professorship, the Moynihan traveling fellowship and the gold medal for the intercollegiate examination. Dr. Thompson is also the editor of the Oxford Textbook of Vascular Surgery and the Oxford Handbook of Vascular Surgery. Dr. Thompson was Chair of the National Specialized Commissioning Clinical Reference Group (2013-2016) for Vascular Services and is a founder of the British Society for Endovascular Therapy (2004). Dr. Thompson was a Council Member of the Vascular Society (2014-2017), and Chairman of the Vascular Society Annual Scientific Meeting (2014-2017). Dr Thompson was the clinical director for three London-wide service reconfigurations (cardiovascular disease, major trauma and emergency services) (2010-2013). Dr. Thompson trained at Cambridge University (1981-1984), St. Bartholomew's Hospital (1984-1987), the University of Leicester (1994) and Adelaide (1998).

Directors and Executive Officers Qualifications

Although we have not formally established any specific minimum qualifications that must be met by each of our officers, we generally evaluate the following qualities: educational background, diversity of professional experience, including whether the person is a current or was a former chief executive officer or chief financial officer of a public company or the head of a division of a prominent international organization, knowledge of our business, integrity, professional reputation, independence, wisdom, and ability to represent the best interests of our shareholders.

The nominating and corporate governance committee of the board of directors prepare policies regarding director qualification requirements and the process for identifying and evaluating director candidates for adoption by the board of directors. The above-mentioned attributes, along with the leadership skills and other experiences of our officers and board of directors members described above, provide us with a diverse range of perspectives and judgment necessary to facilitate our goals of shareholder value appreciation through organic and acquisition growth.

Director Qualifications

R. Kirk Huntsman – Our board believes that Mr. Huntsman's qualifications to serve on our board include his extensive experience in the dental industry, focusing on dental support organizations by integrating cutting-edge technology and better management practices.

Ralph E. Green, DDS, MBA – Our board believes that Dr. Green's qualifications to serve on our board include his extensive experience and relationships in the dental industry, his expertise with clinical trials and executive-level experience with pharmaceutical and dental implant firms.

Anja Krammer – Our board believes that Ms. Krammer's qualifications to serve on our board include her experience as a director and chief executive officer, experience with startup enterprises, her successful leadership roles in securing capital markets funding, and her experience in the pharmaceutical industry.

Mark F. Lindsay – Our board believes that Mr. Lindsay's qualifications to serve on our board include his director experience and his experience in legal, governmental, regulatory and business development within the healthcare industry.

Leonard J. Sokolow – Our board believes Mr. Sokolow's qualifications include his experience as a director and principal executive officer, his legal, accounting, auditing and consulting background, and that he meets the statutory requirements to be identified as an "audit committee financial expert."

Matthew Thompson, M.D. – Our board believes that Dr. Thompson's qualifications to serve on our board include his executive-level experience with a publicly-traded medical technology firm and his extensive medical background.

Director Independence

Our board of directors has affirmatively determined that Ms. Krammer, Mr. Lindsay, Dr. Thompson, Dr. Green and Mr. Sokolow are "independent directors," and Mr. Huntsman is "non-independent director," as defined by the applicable rules and regulations of the Nasdaq.

Board Leadership Structure and Board's Role in Risk Oversight

R. Kirk Huntsman is our Chairman of the Board as well as our Chief Executive Officer. The Chairman has authority, among other things, to preside over board meetings and set the agenda for board meetings. Accordingly, the Chairman has substantial ability to shape the work of our board. We believe that the presence of five independent members of our board ensures appropriate oversight by our board of directors of our business and affairs. However, no single leadership model is right for all companies and at all times. The board recognizes that depending on the circumstances, other leadership models, such as the appointment of a lead independent director, might be appropriate. Accordingly, the board may periodically review its leadership structure. In addition, the board holds executive sessions in which only independent directors are present.

Our board is generally responsible for the oversight of corporate risk in its review and deliberations relating to our activities. Our principal source of risk falls into two categories, financial and product commercialization. Our Audit Committee oversees management of financial risks; our board regularly reviews information regarding our cash position, liquidity and operations, as well as the risks associated with each. The board regularly reviews plans, results and potential risks related to our product offerings, growth, and strategies. Our Compensation Committee oversees risk management as it relates to our compensation plans, policies and practices for all employees including executives and directors, particularly whether our compensation programs may create incentives for our employees to take excessive or inappropriate risks which could have a material adverse effect on our company.

Committees of the Board of Directors

Our board of directors has three standing committees: an Audit Committee, a Compensation Committee and a Nominating and Corporate Governance Committee. The composition and function of each committee are described below.

Audit Committee

The Audit Committee has three members that are independent directors, including Mr. Sokolow, Ms. Krammer and Dr. Green. Mr. Sokolow serves as the chair of the Audit Committee and satisfies the definition of "audit committee financial expert". Our Audit Committee has adopted a written charter (amended on February 25, 2022), and a copy of this charter is posted on the Corporate Governance section of our website, at *www.vivos.com* (click "Investor Relations" and "Governance"). Under such charter, our Audit Committee is authorized to:

- (i) select and retain an independent registered public accounting firm to act as our independent auditors for the purpose of auditing our annual financial statements, books, records, accounts and internal controls over financial reporting; (ii) set the compensation of our independent auditors; (iii) oversee the work done by our independent auditors; and (iv) terminate our independent auditors, if necessary in the Audit Committee's determination;
- select, retain, compensate, oversee and terminate, if necessary, any other registered public accounting firm engaged for the purpose of preparing or issuing an audit report or performing other audit, review or attest services for us;
- (i) approve all audit engagement fees and terms (with the power to sign any engagement letter providing for the same on behalf of our company) and (ii) pre-approve all audit and permitted non-audit and tax services that may be provided by our independent auditors or other registered public accounting firms, and establish policies and procedures for the Audit Committee's pre-approval of permitted services by our independent auditors or other registered public accounting firms on an on-going basis;

- at least annually, to obtain and review a report by our independent auditors that describes: (i) the accounting firm's internal quality control procedures; (ii) any material issues raised by the most recent internal quality control review, peer review or Public Company Accounting Oversight Board ("PCAOB") review or inspection of the firm or by any other inquiry or investigation by governmental or professional authorities in the past five years regarding one or more audits carried out by the firm and any steps taken to deal with any such issues; and (iii) all relationships between the firm and our company or any of its subsidiaries; and to discuss with the independent auditors this report and any relationships or services that may impact the objectivity and independence of the auditors;

- At least annually, to evaluate the qualifications, performance and independence of our independent auditors, including an evaluation of the lead audit partner; and to assure the regular rotation of the lead audit partner at our independent auditors and consider regular rotation of the accounting firm serving as our independent auditors;

- review and discuss with our independent auditors: (i) the auditors' responsibilities under generally accepted auditing standards and the responsibilities of management in the audit process; (ii) the overall audit strategy; (iii) the scope and timing of the annual audit; (iv) any significant risks identified during the auditors' risk assessment procedures; and (v) when completed, the results, including significant findings, of the annual audit;

- review and discuss with our independent auditors: (i) all critical accounting policies and practices to be used in the audit; (ii) all alternative treatments of financial information within generally accepted accounting principles ("GAAP") that have been discussed with management, the ramifications of the use of such alternative treatments and the treatment preferred by the auditors; and (iii) other material written communications between the auditors and management;

- review and discuss with our independent auditors and management: (i) any audit problems or difficulties, including difficulties encountered by our independent auditors during their audit work (such as restrictions on the scope of their activities or their access to information); (ii) any significant disagreements with management; and (iii) management's response to these problems, difficulties or disagreements; and to resolve any disagreements between our auditors and management;

- review with management and our independent auditors: (i) any major issues regarding accounting principles and financial statement presentation, including any significant changes in our management's selection or application of accounting principles; (ii) any significant financial reporting issues and judgments made in connection with the preparation of our financial statements, including the effects of alternative GAAP methods; and (iii) the effect of regulatory and accounting initiatives and off-balance sheet structures on our financial statements;

- inform our independent auditors as requested as to the Audit Committee's understanding of our relationships and transactions with related parties that are significant to our company; and to review and discuss with our independent auditors the auditors' evaluation of our identification of, accounting for, and disclosure of its relationships and transactions with related parties, including any significant matters arising from the audit regarding our relationships and transactions with related parties;

- review with management and our independent auditors: (i) the adequacy and effectiveness of our internal controls, including any significant deficiencies or material weaknesses in the design or operation of, and any material changes in, our internal controls; (ii) any special audit steps adopted in light of any material control deficiencies; (iii) any fraud involving management or other employees with a significant role in such internal controls; (iv) the independent auditors' attestation (as required) of the report on internal controls and the required management certifications to be included in or attached as exhibits to our Annual Reports on Form 10-K or Quarterly Reports on Form 10-Q, as applicable;

- review and discuss with our independent auditors any other matters required to be discussed by applicable requirements of the PCAOB and the Securities and Exchange Commission ("SEC");

- review and discuss with our independent auditors and management our annual audited financial statements (including the related notes), the form of audit opinion to be issued by the auditors on the financial statements and the disclosure under "Management's Discussion and Analysis of Financial Condition and Results of Operations" to be included in our Annual Reports on Form 10-K before such reports are filed, and recommend to our board of directors whether the audited financial statements should be included in the Company's Form 10-K and whether the Form 10-K should be filed with the SEC;

- produce the audit committee report required to be included in our annual or other proxy statements;
- review and discuss with our independent auditors and management our quarterly financial statements and the disclosure under "Management's Discussion and Analysis of Financial Condition and Results of Operations" to be included in our Quarterly Reports on Form 10-Q before such Form 10-Q is filed; and to review and discuss the Form 10-Q for filing with the SEC;
- recommend to our board of directors' policies for our hiring of employees or former employees of our independent auditors;
- establish and oversee our procedures for the receipt, retention and treatment of complaints received about our company regarding accounting, internal accounting controls or auditing matters, or instances of fraud or unlawful conduct, and for the confidential, anonymous submission by our employees of concerns regarding such matters;
- review and discuss with management the material risks faced by us and the policies, guidelines and process by which management assesses and manages our risks, including our major financial risk exposures and the steps management has taken to monitor and control such exposures;
- oversee our compliance with applicable laws and regulations, except with respect to medical, medical regulator and healthcare laws and regulations which are reviewed by the Nominating Corporate Governance Committee, and to review and oversee our policies, procedures and programs designed to promote and monitor such legal and regulatory compliance;
- review with our legal counsel, legal and regulatory matters, including legal cases against or regulatory investigations of our company that could have a significant impact on our financial statements; and
- review, approve and oversee any transaction between us and any related person (as defined in Item 404 of Regulation S-K promulgated by the SEC) and any other potential conflict of interest situations on an ongoing basis, in accordance our policies and procedures, and to develop policies and procedures for the Audit Committee's approval of related party transactions.

Compensation Committee

The Compensation Committee has three members that are independent directors, including Mr. Lindsay, Dr. Thompson and Dr. Green. Mr. Lindsay serves as the chair of the Compensation Committee. Our Compensation Committee has adopted a written charter, and a copy of this charter is posted on the Corporate Governance section of our website, at *www.vivos.com* (click "Investor Relations" and "Governance"). Our Compensation Committee is authorized to:

- review and determine the compensation arrangements for management;
- establish and review general compensation policies with the objective to attract and retain superior talent, to reward individual performance and to achieve our financial goals;
- review and determine our stock incentive and purchase plans;
- oversee the evaluation of the board of directors and management; and
- review the independence of any compensation advisers.

Nominating and Corporate Governance Committee

The Nominating and Corporate Governance Committee has three members that are independent directors, including Dr. Thompson, Ms. Krammer and Mr. Sokolow. Dr. Thompson serves as the chair of the Nominating and Corporate Governance Committee. Our Nominating and Corporate Governance Committee has adopted a written charter, and a copy of this charter is posted on the Corporate Governance section of our website, at *www.vivos.com* (click "Investor Relations" and "Governance"). The functions of our Governance Committee, among other things, include:

- identifying individuals qualified to become board members and recommending directors;
- nominating board members for committee membership;
- developing and recommending to our board corporate governance guidelines;
- reviewing and determining the compensation arrangements for directors; and
- overseeing the evaluation of our board of directors and its committees and management.
- oversee our compliance with applicable medical, medical regulator and healthcare laws and regulations.

Compensation Committee Interlocks and Insider Participation

None of the members of our Compensation Committee, at any time, has been one of our officers or employees, or, during the last fiscal year, was a participant in a related-party transaction that is required to be disclosed. None of our executive officers currently serves, or in the past year has served, as a member of our board of directors or Compensation Committee of any entity that has one or more executive officers on our board of directors or Compensation Committee.

Code of Business Conduct and Ethics

We have adopted a code of business conduct and ethics that applies to all of our employees, officers and directors, including those officers responsible for financial reporting. The code of business conduct and ethics is available at our website at *www.vivos.com* (click "Investor Relations" and "Governance"). We expect that any amendments to the code, or any waivers of its requirement, will be disclosed on our website.

July 2019 Director Resignation Agreements

On July 18, 2019, three directors of our company, Kelly J. McCrann, Paul Lajoie and Dan McKeon, each voluntarily resigned as members of the board of directors. The directors resigned after discussions with the board regarding the optimal size and composition of the board for purposes of our initial public offering and for thereafter operating as a public company. In addition, one director resigned due to the requirements of other professional commitments. In connection with such resignations, we entered into separate Resignation Agreements with each of the resigning directors. Pursuant to such Resignation Agreements, Paul Lajoie, Kelly J. McCrann and Dan McKeon each received options to purchase 8,334 shares of our common stock, which options have an exercise price of $7.50 per share and which expire on July 18, 2024. The Resignation Agreements contain customary confidentiality, non-disparagement and mutual release provisions. We do not believe that the Resignation Agreements are material to our company on an ongoing basis.

2020 Investigation and Recommendations of Joint Board Committee

In February 2020, an issue regarding stock sales by members of our senior management, was brought to the attention of the Audit Committee, and a recommendation was made by our then General Counsel that our company adopt a new formal written policy pertaining to such matters, which had not existed prior to this. Further, and in order to ascertain that no violations of securities law or ethics had occurred, an internal investigation was undertaken by a joint committee of our board consisting of the members of our board's Audit Committee and Nominating and Corporate Governance Committee in accordance with authority delegated to such committees under their respective charters. With the input of internal and external counsel, the investigation concluded that no securities laws had been violated in connection with such sales, and further concluded that enhanced corporate governance (in the form of a formal written policy on private stock sales requiring prior approval of our internal or external legal counsel) should be implemented. Pursuant to the findings and recommendations of the joint committee, an insider stock resale policy and other organizational matters, including changing of duties of certain other employees, were formally adopted by the board on April 27, 2020 and these policies and organizational changes remain in place in all material respects. Notwithstanding the board's approval of these changes, certain organizational matters that were adopted by the board, including relating to our board of directors' oversight over employees, were deemed by Mr. Huntsman and, in certain instances, other members of the board to be inappropriate, impractical, and excessively intrusive in day-to-day management issues, and were opposed. Our board of directors adopted an Insider Trading policy appropriate for a publicly-traded company which is available at our website at *www.vivos.com* (click "Investor Relations" and "Governance").

2020 Removal of Independent Directors and Reconstitution of the Board

On April 30, 2020, a group of our shareholders, representing a majority interest (including R. Kirk Huntsman and G. Dave Singh, our Chairman of the Board and Chief Executive Officer and our former Chief Medical Officer, respectively), acted by written consent to action under Wyoming law to remove all three independent directors then serving on our board of directors: Cody Teets, Carol Coughlin and Robert Mitchell. This action was taken because of disagreements on organizational matters as described above and further because such shareholders believed it to be in the best interest of our company to have a group of independent directors with different experiences, perspectives and skill sets as we transitioned from a private to a public company.

Following the removal of these three directors, the remaining directors appointed Gregg C.E. Johnson, a co-founder of our company who also served as our corporate secretary from 2016 to April 2020, to our board on an interim basis until our next Annual Meeting of Shareholders. Subsequent to their removal, two of the directors, Carol Coughlin and Robert Mitchell, voluntarily entered into Separation Agreements with our company in July 2020. Such Separation Agreements contained customary releases, confidentiality and non-disparagement provisions. As consideration for the entering the Separation Agreements, Ms. Coughlin and Mr. Mitchell each received an equity grant in the amount 16,667 shares and the ability to retain and exercise their previously granted and vested options, and we also committed to providing continued indemnification obligations consistent with our organizational documents and to retain director's and officer's insurance for a period of twenty-four months in connection with Ms. Coughlin's and Mr. Mitchell's prior service on the board. In August 2020, we also entered into a Separation Agreement with Cody Teets pursuant to which we are required to purchase from Ms. Teets and her affiliated entities 13,575 shares of Series B Preferred Stock and warrants to purchase common stock and 16,667 shares of common stock held for an aggregate purchase price of $0.3 million. In addition, pursuant to the Separation Agreement with Ms. Teets, since we did not close a qualified financing, as defined in the agreement of at least $3 million of equity or equity-linked securities by October 28, 2020, Ms. Teets had the option of receiving a modified consideration package consisting of 16,667 shares of unrestricted, fully vested common stock, a grant of stock options to purchase 33,334 shares of common stock at a price of $7.50 that would be fully vested and exercisable and $22 thousand in cash. In November 2020, Ms. Teets elected the modified consideration on her Separation Agreement. We do not believe that the Separation Agreements are material to our company on an ongoing basis.

As a result of the removal of these directors, our remaining board members assembled the slate of director nominees for election at our next annual meeting. Mr. Johnson did not stand for re-election. Our entire slate of directors was elected at our annual general meeting on June 18, 2020 and the current membership includes five independent directors from diverse backgrounds that will assist our business going forward.

October 2020 Derivative Demand and Settlement

On October 22, 2020, two minority stockholders of our company, Lazarus Asset Management, LLC and Paul Lajoie, a former director of our company (the "Demanding Stockholders"), sent a derivative demand to us through counsel asking our board of directors to review and investigate certain recent actions taken by our board of directors, or members thereof, and our senior management including (i) our pursuit of the initial public offering described in this Form 10-K, (ii) our board of directors' previous rejection (on two occasions) of a "reverse merger" transaction proposal made by Lazarus Asset Management, LLC, (iii) purported mismanagement of our corporate assets, and (iv) various matters related to stock sales described above under the caption "2020 Investigation and Recommendations of Joint Board Committee" and other matters, with the Demanding Stockholders asserting that these actions may have constituted breaches of fiduciary duties, gross corporate mismanagement, waste of corporate assets, material misrepresentations and/or insider self-dealing. After discussions with the Demanding Stockholders and their counsel, we ascertained that the Demanding Stockholders were acting for themselves and on behalf of an additional group of minority shareholders, (we refer to the Demanding Stockholders and all such other minority shareholders they acted on behalf of collectively as the "Stockholder Group"). In addition to Mr. Lajoie, the Stockholder Group included another former director of our company, Joe Womack.

While we believe that the assertions of the Demanding Stockholders lacked any merit in fact and in law, rather than expending resources investigating or litigating the claims of the Demanding Stockholders, and in order to proceed with our initial public offering, on November 6, 2020, without admitting or denying any claims asserted by the Demanding Stockholders, we entered into a Settlement and Release Agreement with each member of the Stockholder Group (each a "Settlement and Release Agreement"). Pursuant to the Settlement and Release Agreements, all claims of the Demanding Stockholders were withdrawn with prejudice, and we and the Stockholder Group provided each other with full releases of any claims. In consideration of such withdrawal and releases, the members of the Stockholder Group received: (i) an aggregate of 300,000 shares of our common stock, which shares were subject to a lock-up agreement on terms identical to those executed by other investors in connection with our initial public offering and further were not able be sold by the members of the Stockholder Group until June 15, 2021. Thereafter the members of the Stockholder Group are only selling such shares at the rate of 20% of each Stockholder Group members' respective pro rata portion of such shares per month and (ii) warrants to purchase an aggregate of 325,000 shares of our common stock. Such warrants (x) are exercisable on a cash only basis at a strike price of $7.50, (y) are exercisable for a period of 36 months, beginning June 15, 2021 and ending on [July 15, 2024]. In addition, each member of the Stockholder Group executed a lock-up agreement in connection with our initial public offering with respect to any other securities of our company they may hold on terms identical to those executed by other investors in connection with our initial public offering. Finally, each Settlement and Release Agreement contained customary representations, warranties and covenants, including relating to confidentiality and non-disparagement, and we reimbursed the Demanding Stockholders for $50 thousand of their legal fees associated with the Settlement an Release Agreements.

Item 11. Executive Compensation.

Summary Compensation Table

The following summary compensation table provides information regarding the compensation paid during our fiscal years ended December 31, 2021 and 2020 to our Chief Executive Officer (principal executive officer), our Chief Medical Officer, and our Chief Financial Officer (principal financial officer). We refer to these individuals as our "named executive officers", or "NEOs".

Name and Position		Year	Salary	Bonus	Stock Award	Option Award	Non-Equity Incentive Compensation	Non-Qualified Deferred Compensation	All Other Compensation	Total
R. Kirk Huntsman..	(1)	2021	$344,229	$ -	$ -	$570,300[4]	$ 144,318[5]	$ -	$ 18,302[6]	$1,077,149
Chief Executive Officer		2020	251,784	-	$ -	-	177,847[5]	-	25,705[6]	$ 455,336
G. Dave Singh	(2)	2021	$288,269	$ -	$ -	$ 67,134[4]	$ 75,670[5]	$ -	$ 15,930[6]	$ 447,003
Chief Medical Officer		2020	250,492	-	$ -	-	32,987[5]	-	15,028[6]	$ 298,507
Bradford Amman...	(3)	2021	$230,182	$ -	$ -	$805,560[4]	$ 52,048[5]	$ -	$ 18,302[6]	$1,106,092
Chief Financial Officer		2020	181,167	-	$ -	-	65,348[5]	-	22,423[6]	$ 268,938

(1) Mr. Huntsman has served as Chief Executive Officer of our company since September 2016. Since November 2015, Mr. Kirk Huntsman served as Chief Executive Officer of First Vivos, Inc., a wholly owned subsidiary of our company, which we acquired in August 2016.

(2) Dr. Singh served as Chief Medical Officer of our company from September 2016 through February 2022 and served as our President from September 2016 to June 2019. Since July 2008, Dr. Singh served as Chief Executive Officer of BioModeling Solutions, Inc., a wholly owned subsidiary of our company, which we acquired in August 2016.

(3) Mr. Amman joined our company as Chief Financial Officer in October 2018., Inc.

(4) Stock option award value was based upon a Black-Scholes valuation calculation at the date of the stock option grant. We provide information regarding the assumptions used to calculate the value of all stock option awards made to named executive officers in Note 9 to our audited financial statements for the fiscal year ended December 31, 2021 and 2020.

(5) Represents annual incentive compensation in accordance with terms of individual employment agreement. Compensation for 2020 includes compensation earned but not paid as of December 31, 2021. This compensation was excluded in 2021 ($65,973 for Mr. Huntsman and $32,987 for Dr. Singh).

(6) Company contributions towards health insurance premiums in 2021 and 2020.

Employment Agreements

R. Kirk Huntsman

We entered into an amended employment agreement on October 8, 2020 (the Huntsman Effective Date) with R. Kirk Huntsman. The term of the employment agreement commenced on the Huntsman Effective Date and is subject to termination:

(i) for cause (as defined therein) by us or without cause by Mr. Huntsman, whereby Mr. Huntsman would be entitled to earned but unpaid compensation, bonuses and benefits through the date of termination and his option shares through the date of termination for cause will be deemed vested;

(ii) upon the death or disability of Mr. Huntsman, whereby Mr. Huntsman, upon disability, or Mr. Huntsman's estate, upon death of Mr. Huntsman, will be entitled to receive all compensation and benefits through the date of death or disability as well as continue to receive incentive compensation (as set forth in the agreement) through the end of our fiscal year, as well as salary payable in periodic installments on regular paydays, at the rate then in effect for a period of six months (in addition to the incapacity period, as defined therein, if terminated upon disability) following termination (the "Extended Period") and his option shares through the Extended Period will be deemed vested; or

(iii) without cause by us or for "Good Reason" (as defined therein) by Mr. Huntsman, whereby Mr. Huntsman would be entitled to receive all earned but unpaid compensation, bonuses and benefits through the date of termination as well as continue to receive incentive compensation (as set forth in the agreement) as well as salary payable in periodic installments on regular paydays, at the rate then in effect for a period of one year (if terminated without cause by us) or two years (if terminated upon Good Reason by Mr. Huntsman) following termination and all of his option shares will be deemed vested.

Pursuant to the terms of the employment agreement, in exchange for Mr. Huntsman's services as Chief Executive Officer, we agreed to:

(i) pay Mr. Huntsman an annual base salary of $344,229 during the term of the employment agreement less taxes payable in accordance with employer's normal policies, subject to adjustment by our board of directors at its sole discretion;

(ii) make Mr. Huntsman eligible for incentive cash compensation under a management by objectives incentive plan at 65% of base salary that shall be paid not less than frequently than annually when certain operational targets determined by the Compensation Committee are met;

(iii) make available to Mr. Huntsman employee benefits available to regular full-time executive management employees of our company, including medical and dental insurance, pension and profit-sharing plans, 401(k) plans, incentive savings plans, group life insurance, salary continuation plans, disability coverage and other fringe benefits;

(iv) make available to Mr. Huntsman other equity-based compensation awards under our equity incentive plans and otherwise, which equity awards may be granted pursuant to the authority and sole discretion of our board of directors, together with the Compensation Committee;

(v) make available to Mr. Huntsman high-speed internet access, at our expense, including monthly service charges and maintenance, for use on company business.

Bradford Amman

We entered into an amended employment agreement on October 8, 2020 (the Amman Effective Date) with Bradford Amman. The term of the employment agreement commenced on the Amman Effective Date and is subject to termination:

(i) for cause (as defined therein) by us or without cause by Mr. Amman, whereby Mr. Amman would be entitled to earned but unpaid compensation, bonuses and benefits through the date of termination and his option shares through the date of termination for cause will be deemed vested;

(ii) upon the death or disability of Mr. Amman, whereby Mr. Amman, upon disability, or Mr. Amman's estate, upon death of Mr. Amman, will be entitled to receive all compensation and benefits through the date of death or disability as well as continue to receive incentive compensation (as set forth in the agreement) through the end of our fiscal year, as well as salary payable in periodic installments on regular paydays, at the rate then in effect for a period of six months (in addition to the incapacity period, as defined therein, if terminated upon disability) following termination (the "Extended Period") and his option shares through the Extended Period will be deemed vested; or

(iii) without cause by us or for "Good Reason" (as defined therein) by Mr. Amman, whereby Mr. Amman would be entitled to receive all earned but unpaid compensation, bonuses and benefits through the date of termination as well as continue to receive incentive compensation (as set forth in the agreement) as well as salary payable in periodic installments on regular paydays, at the rate then in effect for a period of one year (if terminated without cause by us) or two years (if terminated upon Good Reason by Mr. Amman) following termination and all of his option shares will be deemed vested.

Pursuant to the terms of the employment agreement, in exchange for Mr. Amman's services as Chief Financial Officer, we agreed to:

(i) pay Mr. Amman an annual base salary of $230,558 during the term of the employment agreement less taxes payable in accordance with employer's normal policies, subject to adjustment by the board at its sole discretion;

(ii) make Mr. Amman eligible for incentive cash compensation under a management by objectives incentive plan at 35% of base salary that shall be paid not less than frequently than annually when operational targets determined by the Compensation Committee are met;

(iii) make available to Mr. Amman employee benefits available to regular full-time executive management employees of our company including medical and dental insurance, pension and profit-sharing plans, 401(k) plans, incentive savings plans, group life insurance, salary continuation plans, disability coverage and other fringe benefits.;

(iv) make available to Mr. Amman other equity-based compensation awards under our equity incentive plans and otherwise, which equity awards may be granted pursuant to the authority and sole discretion of the board, together with the Compensation Committee; and

(v) make available to Mr. Amman paid high-speed internet access, at our expense, including monthly service charges and maintenance, for use on company business.

Termination of Dr. G. Dave Singh

On March 1, 2022, with the unanimous approval of our board of directors, we provided Dr. G. Dave Singh, our founder and Chief Medical Officer, with notice of termination of his employment with us "for cause" pursuant to the terms Dr. Singh's amended and restated employment agreement with us, dated October 9, 2020. As such, Dr. Singh is no longer affiliated with our company effective March 1, 2022. As previously reported, in September 2021 Dr. Singh commenced a sabbatical from our company to serve as an Adjunct Professor at Stanford University. Because Dr. Singh has been on sabbatical, we allocated his responsibilities to other personnel and advisors and do not anticipate that his departure will significantly impact our operations.

Outstanding Equity Awards at Fiscal Year-End

The following table summarizes the number of shares of common stock underlying outstanding equity incentive plan awards for each named executive officer as of December 31, 2021.

Name	Grant Date	Number of Securities Underlying Unexercised Options Exercisable	Number of Securities Underlying Unexercised Options Unexercisable	Option Exercise Price	Option Expiration Date
R. Kirk Huntsman:					
	9-30-17[1]	333,334	-	$ 1.26	8-31-21
	6-16-21[2]	25,000	100,000	5.64	6-16-26
Total for Mr. Huntsman		358,334	100,000		
G. Dave Singh:					
	8-5-21[3]	18,750	11,250	$ 2.71	8-5-26
Bradford Amman:					
	11-8-18[2]	66,667	16,667	$ 7.50	11-8-23
	11-18-19[2]	10,000	6,667	7.50	11-18-24
	3-12-21[2]	20,000	80,000	7.50	3-12-26
	8-31-21[2]	10,000	40,000	5.26	8-31-26
Total for Mr. Amman		106,667	143,334		

(1) Stock option grants vests equally over 12 quarters with the first vesting tranche on the grant date and on the last day of each successive calendar quarter through June 30, 2020.
(2) Stock option grant vests 20% on the grant date and 20% on each successive anniversary through the following four years.
(3) Stock option grant vests 50% on the grant date and 12.5% on each successive quarter through the following year.

Director Compensation

Historically, our directors have not received compensation for their service except for option grants. We adopted a new director compensation program recommended by our corporate governance committee pursuant to which we would make equity-plan based awards to the directors (i) each of our non-employee directors will receive $48,000 cash compensation annually; (ii) chairs of our committees will receive $10,000 cash compensation annually; and (iii) members of our committees will receive $5,000 cash compensation annually. No additional compensation will be provided for attending committee meetings. Our corporate governance committee will continue to review and make recommendations to the board regarding compensation of directors, including equity-based plans. We will reimburse our non-employee directors for reasonable travel expenses incurred in attending board and committee meetings. We also intend to allow our non-employee directors to participate in our equity compensation plans.

Director Compensation Table

The following table sets forth information concerning the compensation of our directors for the fiscal year ended December 31, 2021:

Name		Fees Earned or Paid In Cash	Stock Awards $	Option Awards $ [6]	Total
Leonard J. Sokolow	[1]	$ 36,750	$ -	$ 67,134	$ 103,884
Matthew Thompson, M.D.	[2]	$ 36,750	$ -	$ 67,134	$ 103,884
Mark F. Lindsay	[3]	$ 33,833	$ -	$ 67,134	$ 100,967
Anja Krammer	[4]	$ 33,833	$ -	$ 67,134	$ 100,967
Ralph E. Green, DDS, MBA	[5]	$ 33,833	$ -	$ 67,134	$ 100,967

(1) Mr. Sokolow commenced service as a member of the board on June 19, 2020.
(2) Mr. Thompson commenced service as a member of the board on June 19, 2020.
(3) Mr. Lindsay commenced service as a member of the board on June 19, 2020.
(4) Ms. Krammer commenced service as a member of the board on June 19, 2020.
(5) Mr. Green commenced service as a member of the board on June 19, 2020.
(6) Stock option award value was based upon a Black-Scholes valuation calculation at the date of the stock option grant. We provide information regarding the assumptions used to calculate the value of all stock option awards made to named executive officers in Note 9 to our audited financial statements for the fiscal year ended December 31, 2020.

2017 Stock Option Plan

The 2017 Stock Option and Stock Issuance Plan (or the 2017 Plan) is intended to promote the interests of our company by providing eligible persons in our employ or service with the opportunity to acquire a proprietary interest, or otherwise increase their proprietary interest, in our company as an incentive for them to continue in such employ or service.

Individuals eligible to participate in the Plan are as follows:

1. employees,

2. non-employee members of the board of directors or the non-employee members of the board of directors of any parent or subsidiary, and

3. consultants and other independent contractors who provide services to us (or any parent or subsidiary)

The common stock issuable under the 2017 Plan shall be shares of authorized but unissued or reacquired common stock. The maximum number of shares of common stock which may be issued over the term of the 2017 Plan shall not exceed 1,333,333 shares.

The exercise price per share shall be fixed by the board of directors or its designated committee, as plan administrator, in accordance with the following provisions: the exercise price per share shall not be less than 100% of the Fair Market Value (as defined in the 2017 Plan) per share of common stock on the option grant date. If the person to whom the option is granted is a 10% stockholder, then the exercise price per share shall not be less than 110% of the Fair Market Value per share of common stock on the option grant date. The exercise price shall become immediately due and payable upon exercise of the option.

2019 Stock Option and Stock Issuance Plan

The 2019 Stock Option and Stock Issuance Plan (or the 2019 Plan) is intended to promote the interests of our company by providing eligible persons in our employ or service with the opportunity to acquire a proprietary interest, or otherwise increase their proprietary interest, in our company as an incentive for them to continue in such employ or service.

Individuals eligible to participate in the 2019 Plan are as follows:

1. employees,

2. non-employee members of the board of directors or the non-employee members of the board of directors of any parent or subsidiary, and

3. consultants and other independent contractors who provide services to us (or any parent or subsidiary)

The common stock issuable under the 2019 Plan shall be shares of authorized but unissued or reacquired common stock. The maximum number of shares of common stock which may be issued over the term of the 2019 Plan shall not exceed 2,366,667 shares.

The exercise price per share shall be fixed by the board of directors or its designated committee, as plan administrator, in accordance with the following provisions: the exercise price per share shall not be less than 100% of the Fair Market Value (as defined in the 2019 Plan) per share of common stock on the option grant date. If the person to whom the option is granted is a 10% stockholder, then the exercise price per share shall not be less than 110% of the Fair Market Value per share of common stock on the option grant date. The exercise price shall become immediately due and payable upon exercise of the option.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The following table sets forth information about the beneficial ownership of our common stock as of March 23, 2022, for:

- each person known to us to be the beneficial owner of more than 5% of our common stock;
- each named executive officer;
- each of our directors; and
- all of our named executive officers and directors as a group.

Unless otherwise noted below, the address for each beneficial owner listed on the table is in care of Vivos Therapeutics, Inc., 9137 Ridgeline Blvd., Suite 135, Highlands Ranch, Colorado 80129. We have determined beneficial ownership in accordance with the rules of the SEC. We believe, based on the information furnished to us, that the persons and entities named in the tables below have sole voting and investment power with respect to all shares of common stock that they beneficially own, subject to applicable community property laws. We have based our calculation of the percentage of beneficial ownership on 23,012,119 shares of our common stock outstanding as of March 23, 2022.

In computing the number of shares of common stock beneficially owned by a person and the percentage ownership of that person, we deemed outstanding shares of common stock underlying convertible securities of our company held by that person that are currently exercisable or convertible or exercisable or convertible within 60 days of March 23, 2022. We did not deem these shares outstanding, however, for the purpose of computing the percentage ownership of any other person.

Name Director and Officer Beneficial Owners		Shares of Common Stock Owned	
		Number	Percent
R. Kirk Huntsman	(2)	2,138,834	11.7%
Bradford Amman	(3)	158,667	*%
Mark F. Lindsay	(4)	39,167	*%
Anja Krammer	(5)	39,167	*%
Ralph E. Green, DDS, MBA	(6)	39,167	*%
Leonard J. Sokolow	(7)	39,167	*%
Matthew Thompson, M.D.	(8)	39,167	*%
All executive officers and directors as a group (7 persons)	(9)	2,493,336	13.7%

Name of 5% Stockholder Beneficial Owners		Shares of Common Stock Owned	
		Number	Percent
G. Dave Singh.....	(1)	3,242,205	17.8%
R. Kirk Huntsman.....	(2)	2,138,834	11.7%
All 5% stockholders as a group (2 persons)....	(10)	5,381,039	29.5%

* Less than 1%.

(1) Dr. G. Dave Singh is our founder and former Chief Medical officer and director. He beneficially directly owns 3,219,705 shares of common stock through Himmat LP. Dr Singh and his wife are the members and managers of Himmat LP and may be deemed to have shared voting and dispositive power of all securities beneficially owned by Himmat LP. Includes 22,500 shares of common stock issuable upon exercise of options held by G. David Singh, all of which are exercisable within 60 days. Excludes 7,500 shares of common stock underlying unvested options.

(2) R. Kirk Huntsman is our Chairman of the Board and Chief Executive Officer. He beneficially owns (i) indirectly 1,740,000 shares of common stock through Coronado V Partners, LLC and (ii) directly 333,334 shares of common stock issuable upon exercise of options held by him, of which all 333,334 are exercisable and, 15,500 shares of common stock purchased in the open market. Includes 75,000 shares of common stock issuable upon exercise of options held by R. Kirk Huntsman, all of which are exercisable within 60 days. Excludes 175,000 shares of common stock underlying unvested options. R. Kirk Huntsman and his wife are the members and managers of Coronado V Partners, LLC. As such, Mr. Huntsman may be deemed to have shared voting and dispositive power of all securities beneficially owned by Coronado V Partners, LLC reported herein.

(3) Bradford Amman is our Chief Financial Officer, Treasurer and Secretary. Includes 156,667 shares of common stock issuable upon exercise of options, all of which are exercisable within 60 days, and 2,000 shares of common stock purchased in the open market. Excludes 143,333 shares of common stock underlying unvested options.

(4) Includes 39,167 shares of common stock issuable upon exercise of options held by Mark F. Lindsay, all of which are exercisable within 60 days. Excludes 7,500 shares of common stock underlying unvested options.

(5) Includes 39,167 shares of common stock issuable upon exercise of options held by Anja Krammer, all of which are exercisable within 60 days. Excludes 7,500 shares of common stock underlying unvested options.

(6) Includes 39,167 shares of common stock issuable upon exercise of options held by Ralph E. Green, DDS, MBA, all of which are exercisable within 60 days. Excludes 7,500 shares of common stock underlying unvested options.

(7) Includes 39,167 shares of common stock issuable upon exercise of options held by Leonard J. Sokolow, all of which are exercisable within 60 days. Excludes 7,500 shares of common stock underlying unvested options.

(8) Includes 39,167 shares of common stock issuable upon exercise of options held by Matthew Thompson M.D., all of which are exercisable within 60 days. Excludes 7,500 shares of common stock underlying unvested options.

(9) Includes: (i) 1,116,670 shares of common stock issuable upon exercise of options held by this group, of which 355,833 are exercisable within 60 days. Excludes 760,837 shares of common stock underlying unvested options.

(10) Includes: (i) 613,334 shares of common stock issuable upon exercise of options held by this group, of which 182,500 are exercisable within 60 days. Excludes 430,834 shares of common stock underlying unvested options.

Item 13. Certain Relationships and Related Transactions.

Other than the executive and director compensation and other arrangements, which are described elsewhere in this Annual Report on Form 10-K, and the transactions described below, we are not a party to any related party transactions.

On May 4, 2017, we issued 1,000,000 shares of our Series A Preferred Stock to Dr. G. Dave Singh with a value of $5.00 per share in exchange for intellectual property of Dr. Singh with a value of $5,000,000. In 2018, we redeemed 200,000 shares of the 1,000,000 shares of Series A Preferred Stock held by Dr. G. Dave Singh for $5.00 per share (for an aggregate of $1,000,000). During 2019, Dr. Singh exercised his right to redeem 70,000 shares of the Series A Preferred Stock for $5.00 per share for a total of $350,000. During the first six months of 2020, Dr. Singh exercised his right to redeem 30,000 shares of the Series A preferred stock for $5.00 per share for a total of $150,000. On February 20, 2020, Dr. Singh requested the redemption of an additional 100,000 shares at $5.00 per share. On December 15, 2020, we redeemed all remaining outstanding shares of Series A preferred stock from Dr. Singh for $3,500,000. Our obligation to redeem Dr. Singh's shares of Series A preferred stock was secured by a lien on certain intellectual property assets previously assigned by him to our company. The security agreement terminated upon our redemption of Dr. Singh's Series A Preferred Stock.

We were a party to a management agreement with Upeva, Inc., a company for which our prior Secretary and a former member of the board of directors, Gregg C.E. Johnson serves as chief executive officer. In return for various legal and other consulting services, we paid Upeva a monthly fee of $10,000 until that arrangement terminated on May 1, 2020. As of December 31, 2020, we owed Upeva, Inc. approximately $10,000. This contract expired April 30, 2020 and was not renewed. Additionally, Mr. Johnson is the beneficial owner of 254,902 common shares of our company through Spire Family Holdings, L.P. The payment was made early 2021, no outstanding fees are due.

During the year ended December 31, 2020, Cody Teets, one of our former directors who held $200,000 in our convertible notes issued in 2019, exchanged her outstanding notes for 45,252 shares of our common stock.

For the year ended December 31, 2021 and 2020, options for the purchase of 539,000 and 429,012 shares, respectively, of our common stock were granted to our directors, officers, employees and consultants.

In July 2020, we entered into a Separation Agreement with each of Robert Mitchell and Carol Coughlin. In August 2020, we entered into a Separation Agreement with Cody Teets. For a description of these agreements, see "Management———2020 Removal of Independent Directors and Reconstitution of the Board".

On November 6, 2020, we entered into the Settlement and Release Agreement with the Stockholder Group, which included to former directors of our company, Paul Lajoie and Joe Womack. For a description of this agreement, see "Management————October 2020 Derivative Demand and Settlement."

We have entered into indemnification agreements with each of our directors and entered into such agreements with certain of our executive officers. These agreements require us, among other things, to indemnify these individuals for certain expenses (including attorneys' fees), judgments, fines and settlement amounts reasonably incurred by such person in any action or proceeding, including any action by or in our right, on account of any services undertaken by such person on behalf of us or that person's status as a member of the board of directors to the maximum extent allowed under Wyoming law.

Policies and Procedures for Related Party Transactions

Pursuant to the written charter of our Audit Committee, the Audit Committee will be responsible for reviewing and approving, prior to our entry into any such transaction, all related party transactions and potential conflict of interest situations involving:

- any of our directors, director nominees or executive officers;
- any beneficial owner of more than 5% of our outstanding stock; and
- any immediate family member of any of the foregoing.

Our Audit Committee will review any financial transaction, arrangement or relationship that:

- involves or will involve, directly or indirectly, any related party identified above;
- would cast doubt on the independence of a director;
- would present the appearance of a conflict of interest between us and the related party; or
- is otherwise prohibited by law, rule or regulation.

The Audit Committee will review each such transaction, arrangement or relationship to determine whether a related party has, has had or expects to have a direct or indirect material interest. Following its review, the Audit Committee will take such action as it deems necessary and appropriate under the circumstances, including approving, disapproving, ratifying, canceling or recommending to management how to proceed if it determines a related party has a direct or indirect material interest in a transaction, arrangement or relationship with us. Any member of the Audit Committee who is a related party with respect to a transaction under review will not be permitted to participate in the discussions or evaluations of the transaction; however, the Audit Committee member will provide all material information concerning the transaction to the Audit Committee. The Audit Committee will report its action with respect to any related party transaction to the board of directors.

Anti-Takeover Effects of Certain Provisions of Our Bylaws

Provisions of our bylaws could make it more difficult to acquire us by means of a merger, tender offer, proxy contest, open market purchases, removal of incumbent directors and otherwise. These provisions, which are summarized below, are expected to discourage types of coercive takeover practices and inadequate takeover bids and to encourage persons seeking to acquire control of us to first negotiate with us. We believe that the benefits of increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging takeover or acquisition proposals because negotiation of these proposals could result in an improvement of their terms.

Vacancies. Newly created directorships resulting from any increase in the number of directors and any vacancies on the board of directors resulting from death, resignation, disqualification, removal or other cause shall be filled by a majority of the remaining directors on the board.

Bylaws. Our Certificate of Incorporation and bylaws authorizes the board of directors to adopt, repeal, rescind, alter or amend our bylaws without shareholder approval.

Removal. Except as otherwise provided, a director may be removed from office only by the affirmative vote of the holders of not less than a majority of the voting power of the issued and outstanding stock entitled to vote.

Calling of Special Meetings of Stockholders. Our bylaws provide that special meetings of stockholders for any purpose or purposes may be called at any time only by the board of directors or by our Secretary following receipt of one or more written demands from stockholders of record who own, in the aggregate, at least 15% the voting power of our outstanding stock then entitled to vote on the matter or matters to be brought before the proposed special meeting.

Effects of authorized but unissued common stock and blank check preferred stock. One of the effects of the existence of authorized but unissued common stock and undesignated preferred stock may be to enable our board of directors to make more difficult or to discourage an attempt to obtain control of our company by means of a merger, tender offer, proxy contest or otherwise, and thereby to protect the continuity of management. If, in the due exercise of its fiduciary obligations, the board of directors were to determine that a takeover proposal was not in our best interest, such shares could be issued by the board of directors without stockholder approval in one or more transactions that might prevent or render more difficult or costly the completion of the takeover transaction by diluting the voting or other rights of the proposed acquirer or insurgent stockholder group, by putting a substantial voting block in institutional or other hands that might undertake to support the position of the incumbent board of directors, by effecting an acquisition that might complicate or preclude the takeover, or otherwise.

In addition, our Certificate of Incorporation grants our board of directors broad power to establish the rights and preferences of authorized and unissued shares of preferred stock. The issuance of shares of preferred stock could decrease the amount of earnings and assets available for distribution to holders of shares of common stock. The issuance also may adversely affect the rights and powers, including voting rights, of those holders and may have the effect of delaying, deterring or preventing a change in control of our company.

Cumulative Voting. Our Certificate of Incorporation does not provide for cumulative voting in the election of directors, which would allow holders of less than a majority of the stock to elect some directors.

Choice of Forum

Our bylaws provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (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 us; (ii) any action asserting a claim for breach of a fiduciary duty owed by any director, officer, employee, or agent of ours 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. In addition, our bylaws 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 exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. Our bylaws further provide that any person or entity purchasing or otherwise acquiring any interest in our shares of capital stock shall be deemed to have notice of and consented to these forum selection clauses.

Section 27 of 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, our bylaws provide that the exclusive 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. Section 22 of the Securities Act creates concurrent jurisdiction for state and federal courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder.

Indemnification of Directors and Officers

Our Certificate of Incorporation and bylaws provide that, to the fullest extent permitted by the laws of the State of Delaware, any officer or director of our company, who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative, by reason of the fact that he/she is or was or has agreed to serve at our request as a director, officer, employee or agent of our company, or while serving as a director or officer of our company, is or was serving or has agreed to serve at the request of our company as a director, officer, employee or agent (which includes service as a trustee, partner or manager or similar capacity) of another corporation, partnership, joint venture, trust, employee benefit plan or other enterprise, or by reason of any action alleged to have been taken or omitted in such capacity. For the avoidance of doubt, the foregoing indemnification obligation includes, without limitation, claims for monetary damages against Indemnitee to the fullest extent permitted under Section 145 of the Delaware General Corporation Law as in existence on the date hereof.

The indemnification provided shall be from and against expenses (including attorneys' fees) actually and reasonably incurred by a director or officer in defending such action, suit or proceeding in advance of its final disposition, upon receipt of an undertaking by or on behalf of such person to repay all amounts advanced if it shall ultimately be determined by final judicial decision from which there is no further right to appeal that such person is not entitled to be indemnified for such expenses under our Certificate of Incorporation and bylaws or otherwise.

To the extent that indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or persons controlling our company pursuant to the foregoing provisions, we have been informed that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable. If a claim for indemnification against such liabilities (other than the payment by us of expenses incurred or paid by a director, officer or controlling person of our company in the successful defense of any action, suit or proceeding) is asserted by any of our directors, officers or controlling persons in connection with the securities being registered, we will, unless in the opinion of our counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by us is against public policy as expressed in the Securities Act and will be governed by the final adjudication of that issue.

Transfer Agent

The transfer agent and registrar, for our common stock is VStock Transfer, LLC. The transfer agent and registrar's address is 18 Lafayette Place, Woodmere, New York 11598. The transfer agent's telephone (212) 828-8436.

Item 14. Principal Accounting Fees and Services.

Audit and Non-Audit Fees

Plante & Moran, PPLC ("Plante Moran"), Denver, Colorado (PCAOB ID No. 166) served as the independent registered public accounting firm to audit our books and accounts for the fiscal years ending December 31, 2021 and 2020.

The table below presents the aggregate fees billed for professional services rendered by Plante Moran for the years ended December 31, 2021 and 2020.

	2021		2020	
	Amount	**Percent**	**Amount**	**Percent**
Audit fees	$244,000	100%	$242,000	91%
Audit -related fees	-	0%	-	0%
All other fees	-	0%	25,000	9%
Total	$244,000	100%	$267,000	100%

In the above table, "audit fees" are fees billed for services related to the audit of our annual financial statements, quarterly reviews of our interim financial statements, and services normally provided by the independent accountant in connection with regulatory filings or engagements for those fiscal periods. "Audit-related fees" are fees not included in audit fees that are billed by the independent accountant for assurance and related services that are reasonably related to the performance of the audit or review of our financial statements. These audit-related fees also consist of the review of our registration statements filed with the SEC and related services normally provided in connection with regulatory filings or engagements. "All other fees" are fees billed by the independent accountant for products and services not included in the foregoing categories.

Pre-Approval Policy

It is the Audit Committee's policy to approve in advance the types and amounts of audit, audit-related, tax, and any other services to be provided by our independent registered public accounting firm. In situations where it is not practicable to obtain full Audit Committee approval, the Audit Committee has delegated authority to the Chair of the Audit Committee to grant pre-approval of auditing, audit-related, tax, and all other services up to $100,000. Any pre-approved decisions by the Chair are required to be reviewed with the Audit Committee at its next scheduled meeting. The Audit Committee approved 100% of all services provided by Plante Moran during 2021 and 2020.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) List of documents filed as part of this Annual Report on Form 10-K:

(1) Financial Statements

The financial statements included in Part II, Item 8 of this document are filed as part of this Annual Report on Form 10-K.

(2) Financial Statement Schedules

All schedules are omitted because they are not applicable or the amounts are immaterial or the required information is presented in the consolidated financial statements and notes thereto in Part II, Item 8 above.

(3) Exhibits

The following documents are filed as exhibits to this Annual Report on Form 10-K.

Exhibit No.	Exhibit Description
3.1	Certificate of Incorporation of Vivos Therapeutics, Inc. filed with Delaware Secretary of State on August 12, 2020. (1)
3.2	Amended and Restated Bylaws of Vivos Therapeutics, Inc. (1)
3.3	Certificate of Conversion filed with Delaware Secretary of State on August 12, 2020. (1)
4.1	Form of Stock Certificate. (1)
4.2	Form of Representative's Warrant in connection with the Company's initial public offering. (2)
4.3	Form of Representative's Warrant in connection with the Company's May 2021 follow-on offering. (4)
4.4	Description of Registered Securities. (1)
10.1	Amended and Restated Executive Employment Agreement, dated October 8, 2020, between R. Kirk Huntsman and Vivos Therapeutics, Inc. (1) †
10.2	Amended and Restated Executive Employment Agreement, dated October 8, 2020, between Bradford Amman and Vivos Therapeutics, Inc. (1) †
10.3	Vivos Therapeutics, Inc. 2017 Stock Option and Stock Issuance Plan. (1)
10.4	Vivos Therapeutics, Inc. 2019 Stock Option and Stock Issuance Plan. (1)
10.5	Licensing, Distribution, and Marketing Agreement dated February 12, 2021 between the Company and MyCardio, LLC. (3)+
10.6	Sales Agreement dated February 7, 2022, between the Company and Roth Capital Partners, LLC. (5)
21.1	List of Subsidiaries (*)
23.1	Consent of Plante & Moran PLLC.*
31.1	Certification of the Chief Executive Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. (*)
31.2	Certification of the Chief Financial Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. (*)

Exhibit No.	Exhibit Description
32.1	Certification of the Chief Executive Officer pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. (*)#
32.2	Certification of the Chief Financial Officer pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. (*)#
101.INS*	Inline XBRL Instance Document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

*	Filed herewith
(1)	Incorporated by reference to the Company's Registration Statement on Form S-1, filed with the SEC on October 9, 2020.
(2)	Incorporated by reference to the Company's Registration Statement on Form S-1/A, filed with the SEC on November 19, 2020.
(3)	Incorporated by reference to the Company's Annual Report on Form 10-K, filed with the SEC on March 25, 2021.
(4)	Incorporated by reference to the Company's Current Report on Form 8-K, filed with the SEC on May 12, 2021.
(5)	Incorporated by refence to the Company's Registration Statement on Form S-3, filed with the SEC on February 7, 2022.
†	Includes management contracts and compensation plans and arrangements
+	Certain portions of this exhibit have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K. The Company will furnish supplementally an unredacted copy of such exhibit to the U.S. Securities and Exchange Commission or its staff upon request.
#	A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

Item 16. Form 10-K Summary.

We have elected not to include a summary pursuant to this Item 16.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

VIVOS THERAPEUTICS, INC.

Date: March 31, 2022

By: */s/ R. Kirk Huntsman*
R. Kirk Huntsman
Chairman of the Board and Chief Executive Officer
(principal executive officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities indicated on March 31, 2022.

Signature	Title
/s/ R. Kirk Huntsman R. Kirk Huntsman	Chairman of the Board and Chief Executive Officer (principal executive officer)
/s/ Bradford Amman Bradford Amman	Chief Financial Officer (principal financial and accounting officer)
/s/ Ralph E. Green Ralph E. Green, DDS, MBA	Director
/s/ Anja Krammer Anja Krammer	Director
/s/ Mark F. Lindsay Mark F. Lindsay	Director
/s/ Leonard J. Sokolow Leonard J. Sokolow	Director
/s/ Matthew Thompson Matthew Thompson, MD	Director

EXHIBIT 21.1

Vivos Therapeutics, Inc.
Subsidiaries of the Registrant

Entity Name	Place of Incorporation
First Vivos, Inc.	Texas
BioModeling Solutions, Inc.	Oregon
Vivos Therapeutics (Canada) Inc.	British Columbia
Vivos Management and Development, LLC	Colorado
Vivos Del Mar Management, LLC	California
Vivos Modesto Management, LLC	California
Vivos Therapeutics, DSO LLC, a Colorado limited liability company, and	Colorado
Vivos Providers Network, LLC, a Colorado limited liability company	Colorado

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in Vivos Therapeutics, Inc. and Subsidiaries' Registration Statements on Form S-3 (File No. 333-262554) and on Form S-8 (File No. 333-257050) of our report dated March 31, 2022, with respect to the consolidated financial statements of Vivos Therapeutics, Inc. and Subsidiaries' as of and for the years ended December 31, 2021 and 2020, that appear in this Annual Report on Form 10-K.

/s/ Plante & Moran, PLLC

Denver, Colorado
March 31, 2022

Exhibit 31.1

Certification Pursuant to Rule 13a-14(a)

I, R. Kirk Huntsman, hereby certify that:

1. I have reviewed this Annual Report on Form 10-K of Vivos Therapeutics, Inc.

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c. Evaluated the effectiveness of the registrant disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors:

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 31, 2022

/s/ R. Kirk Huntsman

R. Kirk Huntsman
Chairman and Chief Executive Officer

Exhibit 31.2

Certification Pursuant to Rule 13a-14(a)

I, Bradford Amman, hereby certify that:

1. I have reviewed this Annual Report on Form 10-K of Vivos Therapeutics, Inc.

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors:

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 31, 2022

/s/ Bradford Amman

Bradford Amman
Chief Financial Officer

Exhibit 32.1

CERTIFICATION

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

(18 U.S.C. 1350)

Pursuant to Section 906 of the Sarbanes-Oxley Act of (18 U.S.C. 1350), the undersigned officer of Vivos Therapeutics, Inc., a Delaware corporation (the "Company"), does hereby certify, to the best of such officer's knowledge and belief, that:

(1) The Annual Report on Form 10-K for the year ended December 31, 2021 (the "Form 10-K") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Form 10-K fairly presents, in all materials respects, the financial condition and results of operations of the Company.

Date: March 31, 2022

/s/ R. Kirk Huntsman
R. Kirk Huntsman
Chairman and Chief Executive Officer

This certification shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act, or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act or the Securities Exchange Act.

Exhibit 32.2

CERTIFICATION

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

(18 U.S.C. 1350)

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. 1350), the undersigned officer of Vivos Therapeutics, Inc., a Delaware corporation (the "Company"), does hereby certify, to the best of such officer's knowledge and belief, that:

(1) The Annual Report on Form 10-K for the year ended December 31, 2021 (the "Form 10-K") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Form 10-K fairly presents, in all materials respects, the financial condition and results of operations of the Company.

Date: March 31, 2022

/s/ Bradford Amman
Bradford Amman
Chief Financial Officer

This certification shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act, or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act or the Securities Exchange Act.

Directors, Officers and Corporate Data

Directors

R. Kirk Huntsman
Cofounder, Chairman of the Board, and Chief Executive Officer

Dr. Ralph Green*

Anja Krammer*

Mark Lindsay*

Leonard Sokolow*

Dr. Matthew Thompson*

** Independent Director*

Nondirector Executive Officers

Bradford Amman
Chief Financial Officer, Secretary, and Treasurer

Investor Relations

Julie Gannon
Investor Relations
(720) 442-8113
investors@vivoslife.com

Stockholders and other interested parties may also request information about our company (including our filings with the Securities and Exchange Commission) at vivos.com/investor-relations.

Corporate Headquarters

7921 Southpark Plaza, Suite 210
Littleton, CO 80120

(866) 908-4867

www.vivos.com

Nasdaq Capital Market Symbol: VVOS

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