ProSomnus®, Inc.

2022

Annual Report

No mask, no scalpel,
simply better sleep breathing.

Patient Preferred OSA Therapy™

Fellow Shareholders,

ProSomnus made meaningful commercial, operational, financial, and strategic progress in 2022 toward realizing our vision of being the leading solution for the treatment and management of Obstructive Sleep Apnea.

Record demand for our differentiated, precision medical devices summed up our commercial progress. ProSomnus generated revenues of $19.4 million in 2022, representing 38% growth – an estimated 6x faster than the industry. Feedback cards (n = 8,850) indicated that 97% of patients and providers were satisfied, and 100% would recommend ProSomnus.

Operations rapidly scaled-up manufacturing capacity while expanding gross margins and maintaining our best-in-class service levels. ProSomnus delivered industry leading 98% initial quality and 96% total quality over their three-year treatment lifecycles. And we successfully relocated manufacturing to our new, state-of-the-art facility, quintupling our capacity potential in preparation for future growth.

From a finance perspective, we proudly listed ProSomnus on Nasdaq in 2022 under the ticker "OSA". Our public company transaction strengthened our balance sheet and facilitated access to the resources necessary to fuel ProSomnus' growth and competitive advantages.

ProSomnus also made headway on our key growth initiatives. We achieved important development milestones for our next-generation sensor device. Several studies published in 2022 added to the existing body of evidence associating our devices with excellent, patient preferred outcomes. And we initiated enrollment in our Severe OSA ("SOS") study, designed to support FDA label expansion.

2022 was a transformational year for ProSomnus. I am pleased with our many accomplishments, the incredible contributions of our employees, and progress made toward helping more people breathe better during sleep, every night.

Thank you for your support,

Len Liptak
Chief Executive Officer

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

FORM 10-K

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

For the fiscal year ended December 31, 2022

OR

☐ **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: 001-41567

PROSOMNUS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**88-2978216**
(State of Other Jurisdiction of incorporation or Organization)	(I.R.S. Employer Identification No.)
5675 Gibraltar Drive, Pleasanton, CA	**94588**
(Address of principal executive offices)	(Zip code)

Registrant's telephone number, including area code: (844) 537-5337

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

Title of Each Class	Trading Symbol(s)	Name Of Each Exchange On Which Registered
Common Stock, $0.0001 Par Value per Share	**OSA**	**The Nasdaq Stock Market LLC**
Warrants, each whole warrant exercisable for one share of Common Stock for $11.50 per share	**OSAAW**	**The Nasdaq Stock Market LLC**

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 (§232.0405 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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 232.405 of this chapter) is not contained herein, and will not be contained, to the best of Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

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," and "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. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

The registrant was not a public company as of the last business day of its most recently completed second fiscal quarter and, therefore, cannot calculate the aggregate market value of its voting and non-voting common equity held by non-affiliates as of such date. The registrant's common stock began trading on the Nasdaq Global Market on December 6, 2022. The number of outstanding shares of the Registrant's Common Stock as of March 17, 2023 was 16,037,630.

Documents Incorporated by Reference

Portions of the Company's Proxy Statement for the 2023 Annual Meeting of Stockholders are incorporated by reference in Part III.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This report, including, without limitation, statements under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations," includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, or the Exchange Act. These forward-looking statements can be identified by the use of forward-looking terminology, including the words "believes," "estimates," "anticipates," "expects," "intends," "plans," "may," "will," "potential," "projects," "predicts," "continue," or "should," or, in each case, their negative or other variations or comparable terminology. There can be no assurance that actual results will not materially differ from expectations. Such statements include, but are not limited to, any statements relating to our ability to achieve the anticipated benefits of our business combination, the future financial performance of the combined company following our business combination, the lack of a market for our securities, our growth plans and opportunities, our financial performance, and any other statements that are not statements of current or historical facts.

The forward-looking statements contained in this report are based on our current expectations and beliefs concerning future developments and their potential effects on us. Future developments affecting us may not be those that we have anticipated. These forward-looking statements involve a number of risks, uncertainties (some of which are beyond our control) and other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to, those factors described under the heading "Risk Factors." Should one or more of these risks or uncertainties materialize, or should any of our assumptions prove incorrect, actual results may vary in material respects from those projected in these forward-looking statements. We undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws. These risks and others described under "Risk Factors" may not be exhaustive.

By their nature, forward-looking statements involve risks and uncertainties because they relate to events and depend on circumstances that may or may not occur in the future. We caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and developments in the industry in which we operate may differ materially from those made in or suggested by the forward-looking statements contained in this report. In addition, even if our results or operations, financial condition and liquidity, and developments in the industry in which we operate are consistent with the forward-looking statements contained in this report, those results or developments may not be indicative of results or developments in subsequent periods.

PART I

Item 1. Business

Unless otherwise indicated or the context otherwise requires, references in this section to "ProSomnus," "we," "us," "our," and other similar terms refer to ProSomnus Holdings, Inc. and its consolidated subsidiaries prior to the Business Combination and to ProSomnus, Inc. and its consolidated subsidiaries after giving effect to the Business Combination.

Overview

We are a medical technology company focused on the development, manufacturing and marketing of precision intraoral medical devices, a new non-invasive option for treating and managing patients with mild to moderate obstructive sleep apnea (OSA). Each ProSomnus precision intraoral device is personalized based on the anatomy and treatment plan for each patient. Our patented precision devices are engineered to create unique, consistent and predictable biomechanical advantages that lead to effective, comfortable, economical and patient preferred treatment outcomes for patients with OSA.

Each ProSomnus precision intraoral device consists of a series of two splints, one that fits over the upper teeth and another that fits over the lower teeth. Each splint contains lateral prescription posts that precisely and comfortably posture the jaw forward at a prescribed position that opens the airway in the back of the throat to prevent the airway from collapsing at night, minimizing obstruction, snoring and allowing air to flow more easily. The jaw position can be changed by swapping out an upper or lower splint and replacing it with another splint that contains slightly different lateral prescription posts similar to how clear aligner trays are swapped out for orthodontic treatment.

Our ProSomnus precision intraoral devices are classified by the U.S. Food and Drug Administration (the FDA) as Class II medical devices for the treatment of snoring and mild to moderate OSA. We received pre-market notification and FDA clearance pursuant to Section 510(k) of the Federal Food, Drug, and Cosmetic Act (FDCA) for our first intraoral device in July 2014 and our devices have been commercially available in the United States since August 2014. To date, over 200,000 ProSomnus precision devices have been prescribed for patients.

Sleep apnea is a serious and chronic, respiratory, disease that negatively impacts a patient's sleep, breathing, health, and quality of life. OSA is the most common form of sleep apnea. OSA is a medical condition characterized by a cessation of breathing when the tongue, soft palate, and other related tissues in the back of the throat collapse and obstruct the upper airway during sleep, temporarily decreasing the oxygen concentration in the blood. During an OSA episode, the diaphragm and chest muscles must work harder to overcome the obstruction and open the airway. These episodes disrupt the sleep cycle, reduce airflow to vital organs, stress the body, and create a negative feedback loop. If untreated, OSA increases the risk of high blood pressure, hypertension, heart failure, stroke, coronary artery disease and other life-threatening diseases. In addition to severe comorbidities, untreated OSA is associated with a reduction in everyday quality-of-life, such as an increase in daytime sleepiness, and an impairment of cognitive function which increases the risk of motor vehicle accidents, poor workplace performance and absenteeism.

OSA is a highly prevalent medical disorder. In 2019, Lancet Respiratory Medicine reported that nearly one billion people globally had OSA, including 74 million adults in the United States. Studies report that the prevalence of OSA is increasing, driven by demographic and social health trends. Industry reports and studies estimate that approximately 80% of people with OSA are undiagnosed. Frost and Sullivan estimated that the cost of undiagnosed OSA was $149.6 billion in 2015. In 2010 McKinsey estimated the cost of untreated OSA to be between $65 billion and $165 billion.

We believe that the OSA market is ripe for disruption due to the limitations of current therapies. Continuous Positive Airway Pressure (CPAP), the primary incumbent therapy, delivers air pressure into the patient's airway through a face or nasal mask for the purpose of overcoming obstructions during the night. Many patients find CPAP treatment cumbersome, uncomfortable, claustrophobic, and generally difficult to tolerate, we estimate based on clinical studies that 35%-65% of OSA patients fail to tolerate CPAP.

We believe there is a significant population of people with mild to moderate OSA who seek an alternative to CPAP and are eligible for treatment with ProSomnus devices. Industry reports estimate that approximately 7 million people in the United States have stopped using their CPAP machines, representing a significant immediate market opportunity for ProSomnus. We estimate that the failed CPAP opportunity is growing by 700,000 people in the United States each year. We believe that there is a substantial opportunity outside of the United States and that there is a substantial opportunity for ProSomnus device therapy as a frontline alternative to CPAP for patients mild to moderate OSA, particularly with increasing public awareness and medical education.

Prior to the ProSomnus precision intraoral device, there were few alternatives for OSA patients who refuse or fail CPAP. Historically, treatment alternatives to CPAP have consisted of surgical procedures or legacy dental products. Invasive Surgical procedures, such as hypoglossal nerve stimulation and maxillomandibular advancement, can be irreversible, expensive, and only suitable for a narrow range of patient types such as severe OSA patients within a limited BMI range. Legacy dental products have historically been associated with inconsistent and unreliable performance. We believe that there is both an urgent clinical need and a strong market opportunity for a treatment alternative that is effective, comfortable, non-surgical, convenient, and more economical.

Disease management is another important unmet need and opportunity for providers, payors and patients. OSA is a chronic, lifelong, respiratory disease. None of the current therapies are designed to cure OSA. As a result, healthcare providers, patients and payors must manage the disease for the remainder of each patient's life. Current therapies provide therapeutic data about the function of the device. However, our interviews with leading sleep medicine experts indicate a strong need to efficiently and continuously monitor each patient's physiologic response to the treatment in an effort to better manage the disease. Physiologic data types include heart rate, blood pressure and blood oxygen levels. Disease management is a significant opportunity for ProSomnus and we are developing a novel product that we believe will fulfill the need and benefit clinicians and their patients.

We believe our ProSomnus precision intraoral devices overcome many of the limitations of CPAP and other current treatments of OSA, such as dental products, Hypoglossal Nerve Stimulation and other treatments, by providing the following key benefits:

- **Highly effective for mild and moderate OSA**. ProSomnus precision intraoral devices are highly effective for the treatment of patients with mild and moderate OSA, which accounts for two-thirds of all OSA patients. ProSomnus devices have demonstrated efficacy on par with CPAP for patients with mild to moderate OSA and higher levels of nightly adherence in published studies. The combination of efficacy and nightly adherence suggest that ProSomnus precision intraoral devices are a highly effective treatment option for patients who have OSA.

- **High patient satisfaction**. ProSomnus intraoral devices are customized, more comfortable, and less invasive than CPAP, legacy dental products and surgical treatments, making it a good choice for both patients and providers. In a 31-patient study performed by us and supported by feedback from patients and providers, "A Multi-Center Preference Study of a Novel Oral Appliance Design and Material" published in *Sleep* (May 2021), 100% of patients preferred the ProSomnus intraoral device over CPAP and other legacy dental product therapy devices. Our patient satisfaction advantage is driven by high patient adherence, fewer side effects than CPAP and other therapies, resolution of symptoms, achievement of patient treatment goals, ease of use with minimal cleaning and device maintenance required and minimal disruption to patient bedtime and sleeping habits and routines.

- **Proprietary, innovative technology**. Our ProSomnus intraoral devices are the result of our innovative design capabilities, manufacturing processes and high performance medical grade class VI materials. We have developed proprietary software that uses artificial intelligence to design precision intraoral devices that will precisely fit the unique anatomy and treatment plan for each patient. These designs are rendered using our proprietary, highly automated, and scalable manufacturing process that utilizes algorithm-driven robotic milling and finishing. ProSomnus precision intraoral medical devices offer high-performance medical grade materials and patented, biomechanically superior features compared to alternative therapies. We believe our intellectual property (IP) portfolio, consisting of patents, know-how and trademarks, protects our novel device designs and innovative manufacturing processes and gives us a competitive advantage in the market.

- **Safe and effective treatment for OSA**. Our ProSomnus precision intraoral devices are a safe and effective treatment option for OSA and have received FDA clearance pursuant to Section 510(k) of the FDCA as a Class II medical device for the treatment of snoring and mild to moderate OSA.

- **Economical**. ProSomnus intraoral devices cost significantly less than CPAP, surgical treatment options, and legacy dental products. Based on publicly available insurance reimbursement schedules, the costs associated with delivering ProSomnus intraoral devices are an estimated 80% less than CPAP and 95% less than surgical options. Our cost advantages over legacy appliances are driven by low initial manufacturing costs, significant lower ongoing maintenance costs and fewer adjustments, fewer repair and remakes.

- **Fewer side effects**. ProSomnus intraoral devices are engineered to prevent both short- and long-term side effects. We designed our intraoral devices to mitigate unnecessary jaw pain, discomfort and tooth movement, and we believe that our high adherence rates indicate that patients find any side effects insignificant compared to the health and quality of life improvements provided by our devices. Side effects are defined as events that result in the discontinuation of therapy, which lead to a reduction in adherence and ultimately effectiveness.

The results of multiple scientific investigations, which include both company supported and independent studies that evaluated approximately 1,400 patients in total, indicate that ProSomnus devices are effective, efficacious, demonstrate excellent patient compliance rates, reduce sleep apnea events, improve sleep-related quality of life, reduce snoring, help achieve patients' treatment objectives, and are preferred by patients. In addition, these investigations report high levels of adherence, mitigation of common side effects, strong patient preference for ProSomnus devices over alternatives, and improvements in treatment efficiency. For more information on these studies, see "—Clinical Results and Studies."

The NOTUS3 clinical trial, a third-party investigation published in the Journal of Clinical Sleep Medicine in March 2022, was designed to predict, and evaluate, the efficacy and outcomes of oral appliance therapy for the treatment of OSA. The study reported that 94% of mild and moderate OSA patients were successfully treated using a ProSomnus precision intraoral device. After a six month follow-up period, 85% reported that they achieved their treatment goal with the ProSomnus device and 97% of patients reported a reduction in snoring with a median improvement of six points on a ten-point scale. The Syracuse, Detroit and Multi-center registries, two papers published by the United States Military, and the NOTUS2 study reported similar results for patients with mild to moderate OSA treated with ProSomnus precision intraoral devices.

Two company supported studies, "Efficacy and Effectiveness of the ProSomnus® [IA] Sleep Device for the Treatment of Obstructive Sleep Apnea: EFFECTS Study" (sample size: 28 patients) published in Cureus (June 2, 2021) and "Evaluation of a new oral appliance with objective compliance recording capability: a feasibility study" (sample size: 8 patients) published in Journal of Dental Sleep Medicine (2018;5(2)), reported compliance rates of 93.6% and 87.9%; and mean nightly use of 7.2 and 7.4 hours using ProSomnus devices, making ProSomnus devices the only commercially available OSA treatment to objectively record nightly use that meets the American Academy of Sleep Medicine (AASM) and American Academy of Dental Sleep Medicine (AADSM) recommendations for nightly sleep. The 7.2 hours of mean nightly use is approximately 61% better than what is reported in the literature for CPAP.

Regarding the mitigation of side effects, an independent study, "Assessment of potential tooth movement and bite changes with a hard acrylic sleep appliance: A 2-year clinical study" (sample size: 18 patients) published in Journal of Dental Sleep Medicine (2019;6(2)) found no statistically or clinically significant changes to tooth position, bite or lower anterior teeth position during the 2.3 year mean test period; and an independent study "Comparative assessment of changes in pharyngeal airway space in cases of obstructive sleep apnea with a customized mandibular repositioning appliance — a clinical study" (sample size: 10 patients) published in Sleep Science (2021 Jan-Mar), found that patients treated with ProSomnus devices reported increase in airway space, improvement in sleepiness and less daytime discomfort, a significant improvement in apnea hypopnea sleep apnea index, oxygen desaturation index, respiratory disturbance index, heart rate, snoring and mean oxygen saturation of arterial blood as compared to baselines, and no significant change in dental occlusion.

ProSomnus therapy is a covered benefit for more than 200M beneficiaries of private medical insurance, Medicare, and a growing number of public health insurance programs offered in many countries around the world. In the United States an estimated 70% of treatments are paid for by private insurances, 25% are covered by Medicare and the remaining 5% are paid out-of-pocket by the patient.

Typically, the managing physician screens the at-risk person and orders a sleep test. The majority of sleep tests are now conducted at home, expanding access to care. If the test confirms OSA, the managing physician prescribes a treatment modality. If ProSomnus therapy is prescribed, the patient is referred to a therapy provider trained in oral appliance therapy. The oral appliance therapy provider administers the therapy and refers the patient back to the managing physician for follow up.

Oral appliance therapy providers are typically reimbursed by private medical insurance in the range of approximately $2,000 to $3,500 per patient for intraoral appliance therapy and by Medicare in the range of approximately $1,250 to $1,800 per patient for intraoral appliance therapy. The average amount varies by insurance provider and Medicare jurisdiction. At these reimbursement levels, we believe that intraoral appliance therapy offers therapy providers an attractive ratio of revenue per chair time in comparison to other procedures.

We market and sell our precision intraoral devices to physicians and therapy providers in the United States and in select countries around the world through a direct sales force. We currently have direct sales representatives in the United States and in Europe. Our direct sales force focuses their education, promotional and sales efforts on physicians and therapy providers who have developed a specialty in sleep medicine.Therapy providers are typically dentists, ENTs, nurse practioners, and physcinan assistants who have undergone training in sleep medicine and oral appliance therapy.

We generated revenue of $19.4 million, with a gross margin of 52.9% and a net loss of $7.1 million, for the year ended December 31, 2022, compared to revenue of $14.1 million, with a gross margin of 51.9% and a net loss of $6.0 million, for the year ended December 31, 2021. Accumulated deficit incurred from October 2016, after separating from MicroDental Laboratories, to December 31, 2022 was $45.2 million. Including the accumulated deficit incurred by MicroDental Laboratories prior to the sale of that entity in October 2016, accumulated deficit as of December 31, 2022 was $210.8 million.

Our Competitive Strengths

We believe the continued growth of our company will be supported by the following competitive strengths:

- **Patient preferred therapy**. ProSomnus precision intraoral devices utilize a patented and proprietary combination of technologies to create a treatment experience that patients prefer, based on our studies. Our devices are small and comfortable. Our devices are the only OSA treatment utilizing Medical Grade Class VI rated materials, the most rigorous standard of biocompatibility according to US Pharmacopia, which makes our devices hygienic and easy to keep clean. Our patented iterative titration system makes it easy for patients to use our device and maintain normal bedtime and morning routines.

- **Efficacy for mild to moderate OSA**. ProSomnus precision intraoral devices have demonstrated efficacy for the treatment of mild to moderate OSA. We believe that demonstrating efficacy on par with CPAP will enable us to position ProSomnus therapy as a viable alternative to patients who refuse and fail CPAP or simply prefer a different treatment option.

- **Large, growing market**. Approximately 1 billion people worldwide suffer from OSA, with approximately 74 million located in North America. Approximately 15 – 20% of sufferers in the United States are currently diagnosed, but diagnosis rates are expected to increase in the near term as clinical support, access to care, nearable/wearable diagnostic technologies, health economics and market awareness broaden. We believe that we are uniquely positioned to address this growing market.

- **Front-line therapy**. The AASM and the AADSM updated their guidelines in 2017 to recommend oral appliances as front-line treatment options for patients who preferred them over CPAP.

- **Sales momentum**. Since receiving FDA clearance as a Class II medical device in July 2014, order volumes have grown approximately 86% compounded annually. Over 200,000 ProSomnus precision intraoral medical devices have been prescribed to date. We believe that ProSomnus precision intraoral devices have rapidly become a front-line device of choice for leading sleep dentists in the United States, and we have been named in Inc. Magazine's List of 5,000 Fastest-Growing Private Companies for the past three consecutive years.

- **Strong customer metrics**. In 2022, we experienced a 98% retention rate among our top 100 customers, which are primarily sleep dentists, and a 36% increase in revenue from such customers. Our largest customer represents approximately 5.4% of our revenues. We have a well-established provider network across the United States.

- **Significantly lower cost than CPAP and surgical treatments, and reimbursable by private medical insurance, Medicare and public health insurance programs in many countries**. The cost of therapy is an important consideration for patients and healthcare payors and providers. We believe that our digital prescription and manufacturing process enables us to produce more cost effectively than our competitors. Unlike CPAP and other therapies, ProSomnus precision intraoral devices do not require the types of expensive ongoing consumables and device adjustments that are associated with CPAP and other treatment options. In addition, our ProSomnus intraoral devices are covered by medical insurance and Medicare in the United States, and by social health insurance programs in a growing number of countries around the world.

- **Scalable, mass customized manufacturing platform**. ProSomnus has built a proprietary manufacturing platform that enables high levels of precision, personalized, customized medical device manufacturing without compromising quality, service or the ability to scale. ProSomnus utilizes proprietary device design software and milling robots that are controlled by software to achieve high levels of precision, repeatability, quality, service and scalability.

Our Strategy

Our goal is to become a global leader in OSA solutions by delivering patients and providers effective, safe, economical, non-invasive and patient-preferred medical devices for treating and managing OSA. We believe the following strategies will play a critical role in achieving this goal and our future growth:

- **Expansion of North American direct sales organization**. The core focus of our sales initiative is to expand our direct sales organization in North America. With representatives located in high-value metropolitan areas, the direct sales organization will focus primarily on therapy providers and physicians who are practicing sleep medicine. The main purpose of this initiative is to increase case volume from these therapy providers and physicians by facilitating a referral relationship between them,

helping them expand the sleep medicine aspect of their practices and educating them on the advantages of the ProSomnus intraoral devices. We also intend to further expand our sales to integrated health systems and hospital networks.

- **International expansion**. We are currently initiating the marketing and sales of our ProSomnus intraoral devices in several European countries and intend to further expand our marketing and direct sales into international markets. ProSomnus devices have obtained a CE mark, and have conformed with additional regulatory requirements for target countries.

- **Establish ProSomnus as the brand of choice**. Our marketing team is working to establish ProSomnus as the "brand of choice" among dentists and physicians who practice sleep medicine. We believe that marketing will raise awareness of our products and services, predispose sleep medicine practitioners to doing business with us and generate qualified leads for sales organization through sponsorship of continuing education seminars, conferences and events.

- **Science-backed marketing**. We continue to develop scientific data to further validate the advantages of ProSomnus devices, engage key opinion leaders who perform research, and support the goal of establishing ProSomnus as the leading brand in sleep medicine. We expect that data will continue to be developed with the intent of having studies published in peer-reviewed journals and presented at conferences, as well as utilized in sales and marketing materials.

- **Line extensions**. We intend for device line extensions to focus on enabling ProSomnus to capture a larger share of treatments for patients with OSA, snoring and other related sleep disordered breathing conditions. We expect that each line extension will be designed to optimize ProSomnus devices for a wider range of case types, treatment philosophies, and indications. We expect that each line extension will utilize our unique manufacturing platform and potentially create additional opportunities for intellectual property.

- **Remote monitoring services**. We received FDA clearance for an intraoral device that enables remote patient monitoring services in November 2020. The sales of such remote monitoring services in connection with our intraoral devices could result in an additional recurring revenue stream that is reimbursable by insurance. Our remote patient monitoring services will be based on the incorporation of a sensor into the ProSomnus intraoral devices that provides continuous monitoring of physiological health data that physicians want and cannot typically obtain from CPAP or other intraoral appliance therapy devices. Our market research indicates that our remote monitoring services could be a significant driver of greater market acceptance and expansion and result in significant future revenues.

- **Manufacturing automation**. We continue to invest in process improvements and technologies that improve our quality and service levels and expand our capacity to meet demand for our devices. We have developed proprietary software the automates the design of our precision, mass customized devices. We have developed proprietary software the controls our milling robots. We believe there is significant opportunity to continue improving quality, service and yield rates by continuously improving the software that controls our design and milling processes, as well as automation technologies pertaining to pre-manufacturing and finishing. Automation will have the added benefit of increasing manufacturing efficiency and delivering higher gross margins over time.

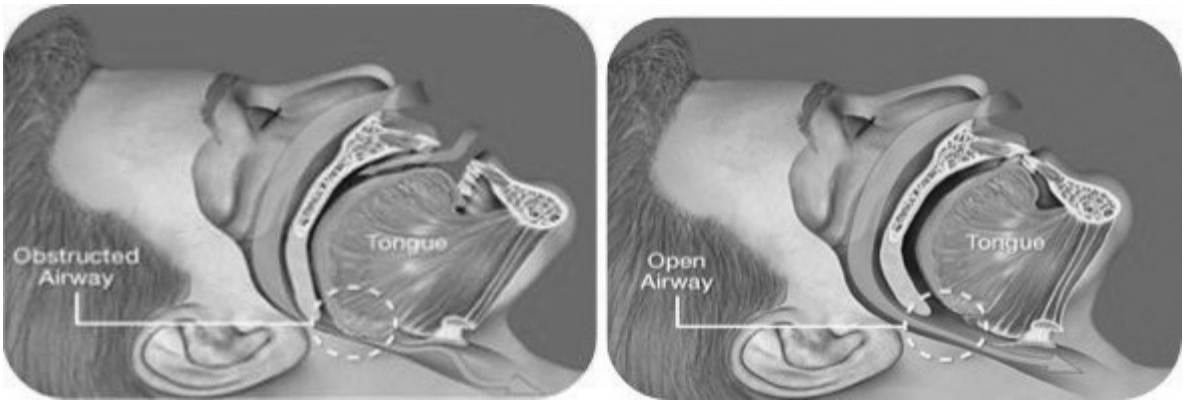
- **Label expansion.** ProSomnus is currently working with the FDA to expand our labeling to include severe OSA. We are actively enrolling in our Severe Obstructive Sleep Apnea Study (SOS). The performance goals have been set with the FDA for the purpose of label expansion.

Market Opportunity

About Obstructive Sleep Apnea (OSA)

OSA is a medical condition characterized by a cessation of breathing, when the tongue, soft palate and other related tissues in the back of the throat collapse and obstruct the upper airway during sleep, temporarily decreasing the oxygen concentration in the blood. During an OSA episode, the diaphragm and chest muscles must work harder to overcome the obstruction and open the airway. These episodes disrupt the sleep cycle, reduce airflow to vital organs, stress the body, and create a negative feedback loop. The lack of airflow can last anywhere from ten seconds to more than a minute, and in severe cases may occur 30 or more times during an hour of sleep. The reduction in blood oxygen triggers an arousal that transiently wakens the patient and opens the airway, leading to a temporary restoration of normal breathing. This cycle occurs throughout the night, decreasing the overall quality of a patient's sleep, negatively affecting a patient's breathing, health and significantly reducing their quality of life.

The following diagram depicts a typical OSA event in which the base of the tongue falls back and restricts airflow.



The severity of OSA is measured by the frequency of apnea or hypopnea events per hour. Apneas are a complete restriction of the airway and hypopneas are a greater than 50% restriction in the airway, both of which are accompanied by a significant decrease in the oxygen levels in the blood. The total number of apneas and hypopneas per hour of sleep is referred to as the Apnea-Hypopnea Index, or AHI. The severity of OSA is based on the following AHI ranges:

- Normal range: AHI < 5 events per hour
- Mild OSA: 5 ≤ AHI < 15 events per hour
- Moderate OSA: 15 ≤ AHI < 30 events per hour
- Severe OSA: AHI ≥ 30 events per hour

Symptoms and Diagnosis of Obstructive Sleep Apnea

Patients struggling with OSA typically have signs and symptoms but are unaware of their condition. Patients who are obese, male or of advanced age are at higher risk for OSA. A common first indicator is that a patient is a heavy snorer. Beyond snoring, a patient may also experience lack of energy, headaches, depression, memory or concentration problems, excessive daytime sleepiness, drowsy driving, nighttime gasping and dry mouth.

The impact of heavy snoring creates unrest for both the patient and his or her bed partner. The bed partner's inability to sleep without interruption often drives the patient to obtain medical advice, usually from their frontline healthcare provider, which is typically a primary care physician or a dentist. If the provider believes the patient may suffer from OSA, they will refer the patient to a sleep medicine physician for diagnosis. The sleep physician will then typically order a sleep study, or polysomnogram, to determine a definitive diagnosis of OSA. This type of sleep study often requires the patient to stay overnight at the sleep center, attached to a variety of monitors and sensors that measure the patient's airflow, sleep quality, blood oxygen levels and breathing patterns. More recently, physicians have begun prescribing home sleep tests, or HSTs, in lieu of in-office polysomnograms, to help diagnose OSA. We expect that as the use of HSTs, which are more convenient for patients than in-office polysomnograms, continues to increase, the number of patients diagnosed with OSA will also increase.

Comorbidities Associated with OSA and Economic Costs if Untreated

Repetitive cessation of breathing during sleep can have a substantial negative impact on affected patients and their quality of life. Published research shows a strong correlation between OSA and negative health outcomes, including:

- heart failure;
- hypertension;
- stroke;
- atrial fibrillation;
- type 2 diabetes;

- obesity;
- heart attack;
- acute coronary syndrome; and
- depression.

An 18-year longitudinal follow-up study at the University of Wisconsin demonstrated the risk of these co-morbidities. The 1,522-person Wisconsin Sleep Cohort sample reported significantly reduced survival rates for individuals with untreated OSA.

Untreated OSA is also associated with significantly higher healthcare costs. A report by Frost and Sullivan, commissioned by the American Academy of Sleep Medicine, estimates that the cost of untreated OSA was $149.6 billion in 2015, and that the people with untreated OSA are three times more expensive than people with OSA who are treated. In 2010 McKinsey estimated the cost of untreated OSA to be between $65 billion and $165 billion.

Prevalence of Sleep Apnea

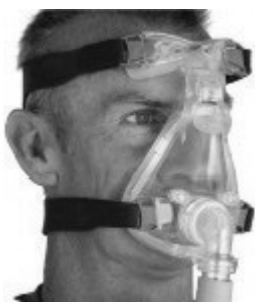
We believe the prevalence of OSA is large and growing. In 2019, *The Lancet Respiratory Medicine* estimated that nearly 1 billion adults aged 30 – 69 years have mild to severe OSA globally and approximately 74 million adults aged 30 – 69 years have mild to severe OSA in North America, suggesting that the condition is both underdiagnosed and under-recognized. There are two types of sleep apnea: OSA and Central Sleep Apnea, or CSA. OSA is the most common form of sleep apnea and is caused by a physical obstruction of the airway. By contrast, CSA is far less common and is caused by the brain's inability to send appropriate signals to the muscles in the chest that control breathing. Our ProSomnus precision intraoral medical devices are designed to treat patients with OSA.

Current Treatments for OSA and their Limitations

There are several treatment options for OSA. CPAP is the most commonly prescribed therapy for patients with OSA. The other common approaches for treating patients with OSA are surgical procedures (including implantable devices) and intraoral appliance therapy devices.

CPAP

CPAP is delivered through a face or nasal mask that connects through a hose to a bedside air pump. The pump forces air through the hose to the mask and down the patient's throat, keeping the airway open and allowing the patient to breathe. In order for treatment with CPAP to be most effective, the mask must form an airtight seal on the patient's face or nose and the mask must be worn every night.



CPAP is the incumbent therapy and has demonstrated improvements in AHI during sleep tests. Patient-reported sleep quality and reductions in daytime sleepiness associated with the number of hours of use. Many patients who use a CPAP device report symptom relief, increased energy levels, and an improvement in mental sharpness during the day.

Despite the efficacious treatment CPAP offers, overall nightly therapeutic effectiveness is limited by low patient compliance. Based on published literature, we estimate that only approximately 35% to 65% of patients prescribed a CPAP device are compliant with the therapy. Commonly cited reasons patients fail to use their CPAP device on a regular basis include mask discomfort, mask leakage, pressure intolerance, skin irritation, nasal congestion, nasal drying, nosebleeds, claustrophobia, social concerns, and lack of intimacy. Low patient compliance persists despite the development of various CPAP device improvements and auxiliary technologies designed to improve patient comfort and treatment through a variety of methods, including coaching, patient education and remote monitoring.

Legacy Dental Product Therapy Devices

Legacy dental product therapy is an alternative treatment to CPAP that is preferable for many patients due to comfort, convenience and the lack of side effects in comparison with CPAP. However, legacy dental product therapy devices suffer from imprecision, which can limit the efficacy and predictability of the treatment. When dental product manufacturers create their devices, their process capability is typically plus or minus several millimeters, which can lead to the finished oral appliance deviating significantly from the patient's anatomy, prescription, and treatment plan, thereby compromising efficacy, comfort and overall performance. A difference of several millimeters is thought to be clinically significant. The mean airway width for a patient with OSA is approximately 10 millimeters. Several studies establish the dose dependent relationship between oral appliance jaw repositioning and treatment efficacy, further indicating the importance of precision when repositioning the mandible.

Surgical Procedures

In cases of OSA where CPAP has failed or patients have discontinued treatment, surgery may be an alternate therapy. Three of the primary surgical procedures for treating OSA are uvulopalatopharyngoplasty, or UPPP, maxillomandibular advancement, or MMA, and hypoglossal nerve stimulation, or HNS. In a UPPP procedure, the surgeon remodels the structure of the airway by removing excess tissue that is believed to be responsible for obstructing the airway. This can include the uvula, part of the soft palate or roof of the mouth, excess throat tissue, tonsils, adenoids and part of the tongue. Although the most common surgical procedure for OSA, UPPP has only a 33% to 50% success rate, and its efficacy fades with time. In an MMA procedure, a surgeon reconstructs the lower jaw by breaking the jaw and inserting spacers to reposition it forward by approximately 10 millimeters. This surgery is thought to be more effective than UPPP, but it is considered an extreme procedure due to the dramatic change in physical appearance it can cause. Both of these are invasive inpatient procedures that irreversibly alter the patient's anatomy and require extended and painful recovery periods. The typical recovery period for a UPPP procedure is three weeks, and for an MMA procedure is several months. While these procedures may be effective in reducing OSA, the success rates vary widely.

Other surgical options for the treatment of OSA include hypoglossal nerve stimulation. HNS is a surgically implanted system that includes a pulse generator implanted in the patient's body, an implanted stimulation lead that delivers the signal from the pulse generator to the hypoglossal nerve, an implanted sensing lead that measures breathing patterns, and a remote control. Currently HNS has a very narrow indication for use, limited to severe OSA patients who have failed CPAP. In addition to being invasive, HNS is expensive.

We believe there is a significant population in the United States and globally with OSA who are eligible for ProSomnus precision intraoral devices and are unable to use or get consistent benefit from CPAP. We believe that there is both an urgent clinical need and a strong market opportunity for an effective, non- invasive, convenient and economical alternative to CPAP and surgical procedures to treat OSA.

ProSomnus Precision Intraoral Medical Devices — Our Solution for Treatment of OSA

We believe that ProSomnus precision intraoral medical devices are well positioned to address the limitations of competing OSA therapies by offering a more effective, convenient and economical therapy for patients, providers and payors. Utilizing a proprietary precision manufacturing platform, ProSomnus intraoral devices are more precise, comfortable, customizable and easier to use than other current treatments. We believe that ProSomnus precision intraoral devices offer the opportunity for better effectiveness, adherence, outcomes and fewer side effects than CPAP.

ProSomnus precision intraoral medical devices are personalized for each patient based on their unique anatomy, treatment plan and prescription, similar to eyeglass lenses or clear aligners for orthodontic treatment. Each ProSomnus intraoral device consists of a series of two splints, one that fits over the upper teeth and another that fits over the lower teeth. Each splint contains a lateral prescription post that precisely and gently postures the jaw at the prescribed position and opens the airway in the back of the throat to prevent the airway from collapsing at night, minimizing obstructions, snoring and allowing breathing to flow more easily. Jaw position can be changed by swapping out an upper or lower splint and replacing it with another splint that contains a slightly different lateral prescription post position, like how clear aligner trays are swapped out for orthodontic treatment.

We believe that precision prescription transfer enables ProSomnus devices to perform better than other treatment options, including traditional oral appliances. A study supported by ProSomnus was designed to evaluate the prescription transfer precision of several leading traditional oral appliances and ProSomnus devices. One millimeter of variance to the prescribed jaw position is generally recognized as a clinically significant level of variance. The study reported that traditional oral appliances exhibited approximately 3.7 millimeters variance to the prescribed jaw position. The implication is that approximately 29% of traditional oral appliances satisfy the prescription transfer specification, with 71% falling outside of the prescription transfer specification limit. The study also reported that ProSomnus devices demonstrated approximately 0.3 millimeters of variance to the prescribed jaw position, well within the one-millimeter threshold. The implication is that 99% of ProSomnus devices fall within the prescription transfer specification. We believe that our precision prescription transfer advantage, enabled by our unique digital manufacturing platform, translates into performance benefits for the provider and patient.

ProSomnus intraoral devices are designed to make it easy for the patient to follow a normal bedtime routine and adhere to therapy, every night. For example, patients can talk, read, watch TV and drink water while wearing their ProSomnus intraoral device. Patients can go to the bathroom without removing it. They can travel with it. ProSomnus intraoral devices are easy to keep clean, do not require power, water or the bulky equipment and accessories associated with CPAP, and are easy to replace if lost.

Patient Treatment Process

Most potential patients learn they may be a possible candidate for OSA therapy from their bedpartners, physician examinations, word of mouth recommendation, search engines and medical websites, education and advertising campaigns, and/or dentist examinations. Some useful predictive information can be obtained from self-reported questionnaires given to the patient in advance of a formal evaluation, and this procedure may simplify the clinical assessment of patients. Medical organizations are beginning to include screening for OSA in routine physical examinations or during other medical evaluations, particularly for patients who are symptomatic.

We believe that dentists are uniquely positioned to identify patients who are at risk of OSA and refer patients to physicians for diagnosis. During routine dental examinations, dentists can identify certain anatomical risk factors such as a small upper airway. They can ask a few simple screening questions or provide questionnaires to further examine a patient's likelihood of having OSA. Data indicates that most patients visit their dentists more frequently than they visit their primary care physician, placing dentists in an important position for OSA screening. The AASM asserts that dentists have the access and expertise to screen for OSA and refer patients for diagnosis, and the American Dental Association has recommended that all dentists perform OSA screening. The combination of these facts places dentists in a unique position for the screening of OSA and will likely increase awareness and diagnosis rates over time.

If a primary care physician or dentist believes that a patient may have OSA, he or she will generally refer the patient to a sleep physician, who will typically order either a home sleep apnea test or a full polysomnography test, which provides detailed information on sleep state, respiratory behavior and gas exchange abnormalities, in addition to a range of other variables including body position, heart rate and rhythm, and muscle tone and activity. The sleep physician then makes a diagnosis based on the results of the sleep test.

If a patient is diagnosed with sleep apnea and is a candidate for intraoral appliance therapy, the physician will prescribe intraoral appliance therapy as the treatment modality and make a referral to a sleep dentist. The sleep dentist then prescribes a particular intraoral appliance therapy device, such as one of our ProSomnus precision intraoral devices. The dentist typically takes an impression of the patient's teeth using an intraoral scanner and sends the data and a prescription to us. The ProSomnus precision intraoral device is then designed based on the provided digitized patient information and the dentist's prescription. A milling robot fabricates the device from medical grade (U.S. Pharmacopeia (USP) Class VI compliant) polymer, using a series of milling tools that are controlled by milling strategy software. The device is then labeled and polished. The finished device is then packaged and sent to the dentist for delivery to the patient.

The manufacture of a ProSomnus intraoral device typically takes seven production days, in comparison with several weeks for legacy dental product. Upon receipt of the customized ProSomnus intraoral device by the dentist, the patient will visit the dentist for the fitting of the device. The patient may then take a new post- treatment home sleep apnea test or a polysomnography test to determine the efficacy of the ProSomnus intraoral device on the patient. Though dental sleep providers report that many patients are treated without

need for adjustment, dentists easily adjust the treatment by instructing the patient to swap upper or lower splints that contain different prescription settings.

Market Opportunity

The North America obstructive sleep apnea device market was estimated to be $3.47 billion dollars in 2021 (Market Data Forecast). The market is forecasted to expand at a compound annual growth rate of 8.1% between 2022 and 2027 (Market Data Forecast). Research estimates that there are 74 million adults in North America with Obstructive Sleep Apnea, of which 18 million have been diagnosed. The underlying drivers of growth are the obesity and aging population trends. Studies indicate that the incidence and severity of OSA is correlated with obesity and age. We believe there is a significant population of people in North America with mild to moderate OSA who seek an alternative to CPAP and are eligible for treatment with ProSomnus devices. Industry reports estimate that approximately 7 million people with OSA of all severities in the United States have stopped using CPAP, representing a $4 billion dollar immediate opportunity for ProSomnus. We estimate that the failed CPAP opportunity is growing by 700,000 people in the United States each year. We believe that there is a substantial opportunity outside of the United States. We also believe there is a substantial opportunity for ProSomnus device therapy as a frontline alternative to CPAP for patients mild to moderate OSA, particularly with increasing public awareness and medical education. And there is an opportunity for ProSomnus's next generation devices to enable more efficient disease management via remote patient monitoring technologies.

Clinical Results and Studies

A significant and growing body of published clinical evidence, including approximately 1,400 unique patient data points from multiple studies evaluated across several independent and company supported clinical investigations, supports the efficacy, compliance, safety, patient preference and symptom alleviation of ProSomnus therapy for patients with OSA.

Below is a high level summary of these studies:

Study Name	Sample Size	Classification	Key Finding	Reference
Military 3	360	Independent	Improved Quality of Life	US Army Public Health Center Report: Obstructive Sleep Apnea Surveillance and Oral Appliance Therapy Evaluation, Active Duty U.S. Army, 2014–2019, May 2022
Military 1	288	Independent	88.1% success for all severities	Knowles S, Dekow M, Williamson ML. Oral Appliances for OSA Treatment: Meeting the Quadruple Aim. Mil Med. 2021 Aug 19:usab316. doi: 10.1093/milmed/usab316. Epub ahead of print. PMID: 34411239.
San Diego Registry . . .	211	Independent	AHI and ESS Improved	Rohatgi R. Is the Relationship Between OAT Outcomes, Dosage and OAT Device Type as Expected? A Private Practice, Retrospective Cohort Study. Journal of Dental Sleep Medicine. Vol. 6, No.3 2019. Abstract #030.
Syracuse	115	Independent	91% success for mild/moderate	Sall E. Precision Oral Appliance Therapy: The Prime-Time Treatment for OSA. World Sleep Congress. Rome, Italy. Poster Abstract #289. March 2022.
NOTUS3	58	Independent	94% success for mild/moderate	Mosca EV, Bruehlmann S, Zouboules SM, et al. In-home mandibular repositioning during sleep using MATRx plus predicts outcome and efficacious positioning for oral appliance treatment of obstructive sleep apnea. J Clin Sleep Med. 2022;18(3):911–919.
Multi-Center	55	Company Supported	98% success for mild/moderate	Smith K; Carollo J; Desai A; Murphy M. Efficacy of a Novel Precision Iterative Device and Material. World Sleep Congress. Rome, Italy. Poster Abstract #081. March 2022.
Detroit Registry	50	Independent	92% success for mild/moderate	Murphy M, Munro K. Device Design's Impact on Dose in Oral Appliance Therapy. Journal of Dental Sleep Medicine. Vol. 8, No. 3 2021. Abstract #004.
NOTUS2	48	Independent	90% success for mild/moderate	Remmers JE, Topor Z, Grosse J, Vranjes N, Mosca EV, Brant R, Bruehlmann S, Charkhandeh S, Zareian Jahromi SA. A Feedback-Controlled Mandibular Positioner Identifies Individuals With Sleep Apnea Who Will Respond to Oral Appliance Therapy. J Clin Sleep Med. 2017 Jul 15;13(7):871-880. doi: 10.5664/jcsm.6656. PMID: 28502280; PMCID: PMC5482578.
Multicenter preference .	31	Company Supported	100% preferred	Elliott E, Ehtessabian J, Murphy M, Rein J, Seltzer N, Schwartz D, Shah S, Smith K. A Multi-Center Preference study of a Novel Oral Appliance Design and Material for Better Provider, Physician, Patient and Payer Acceptance. SLEEP Journal. Vol. 44, Abstract Supplement, 2021. Abstract #440. Page A 174.

EFFECTS Study	28	Company Supported	93.6% compliance	Stern J, Lee K, Kuhns D, et al. (June 02, 2021) Efficacy and Effectiveness of the ProSomnus® [IA] Sleep Device for the Treatment of Obstructive Sleep Apnea: EFFECTS Study. Cureus 13(6): e15391. DOI 10.7759/cureus.15391
Alaska 3	26	Independent	62% improvement	Hu JC, Comisi JC. Vertical dimension in dental sleep medicine oral appliance therapy. Gen Dent. 2020 Jul-Aug;68(4):69-76. PMID: 32597782.
Military 2	24	Independent	87.5% success for all severities	Kang CRS, Knowles S, Dekow M. The Success of Oral Appliance Therapy Based on Symptom-Driven Titration. Mil Med. 2022 Aug 20:usac248. doi: 10.1093/milmed/usac248. Epub ahead of print. PMID: 35986605.
Carlton Study.	20	Independent	75% improvement	Carlton D, Is Selecting the Appropriate Sleep Device Important for You and Your Patient Important? Dental Sleep Practice, Summer 2016.
UoP.	18	Independent	No change in teeth/bite	Vranjes N, Santucci G, Schulze K, Kuhns D, Khai A. Assessment of potential tooth movement and bite changes with a hard-acrylic sleep appliance: A 2-year clinical study. J Dent Sleep Med. 2019;6(2)
India	10	Independent	No change in teeth/bite	Aziz R, Somaiah S, Kalha AS, Reddy G, Muddaiah S, Shetty B. Comparative assessment of changes in pharyngeal airway space in cases of obstructive sleep apnea with a customized mandibular repositioning appliance - a clinical study. Sleep Sci. 2021 Jan-Mar;14(Spec 1):16-24. doi: 10.5935/1984-0063.20200072. PMID: 34917269; PMCID: PMC8663729.
Alaska 2	8	Company Supported	87.9% compliance	Hu J, Liptak L. Evaluation of a new oral appliance with objective compliance recording capability: a feasibility study. Journal of Dental Sleep Medicine. 2018;5(2):47–50.
Alaska 1	7	Company Supported	71% improvement	Hu et al, Dental Sleep Practice, March 2015.

Efficacy

Based on our own market intelligence surveys and third-party surveys, efficacy is one of the primary considerations for a managing physician when selecting a treatment modality.

The table below highlights the key findings from 5 studies comprising 326 unique patients that evaluate the efficacy of treating patients with mild to moderate OSA utilizing ProSomnus precision intraoral devices. ProSomnus precision devices demonstrated a weighted average success rate of 93% in these studies that reported data for patients with mild and moderate OSA.

Study Reference	Sample Size	Success Criteria	Key Finding
Sall et al, World Sleep Congress, 2022.	115	AHI < 10	91% Success Mild/Mod OSA
Mosca et al, JCSM, 2022	58	ODI < 10	94% Success Mild/Mod OSA
Remmers et al, JCSM, 2017.	48	ODI < 10	90% Success Mild/Mod OSA
Murphy et al, JDSM, 2021.	50	AHI < 10	92% Success Mild/Mod OSA
Smith et al, World Sleep Congress, 2022	55	AHI < 10	98% Success Mild/Mod OSA
Total	**326**	**Average**	**93% Success Mild/Mod OSA**

Seven additional studies, including 936 unique patients, report on the efficacy associated with treating OSA patients of all severity levels with ProSomnus precision intraoral devices. Three independent studies published by the US Army, US Army Public Health Center Report on Obstructive Sleep Apnea Surveillance in 2022, Knowles in Military Medicine 2021, Kang in Military Medicine 2022, evaluated 360, 288, and 24 patients, respectively. The US Army Public Health Center Report, 2022, found that patients treated indicated improvements in sleep and quality of life. Knowles, 2021, reported that 88.1% of patients with all severities of OSA were successfully treated, and that patients treated with precision intraoral devices represented significant cost savings over alternative treatments such as CPAP. Kang, 2022, concluded that 87.5% of patients with OSA of all severities were successfully treated. Rohatgi in JDSM 2019, reported that 211 consecutively treated patients with ProSomnus precision devices experienced statistically and clinically significant improvements in OSA events and sleepiness even with practicing a conservative approach to jaw repositioning. Hu et al in General Dentistry 2020, reported a 62% mean reduction of OSA events without titrating the prescription for 26 patients diagnosed with OSA. Carlton in Dental Sleep Practice 2016, and Hu in Dental Sleep Practice 2015, reported 75% and 71% improvement in OSA events for 20 and 7 patients, respectively.

Compliance

Two company supported studies, published in peer-reviewed medical journals involving thirty-six total patients, evaluated patient compliance with ProSomnus precision intraoral devices. Both studies utilized ProSomnus devices fitted with thermo-sensors to objectively record nightly use. The table below highlights the key findings from these studies.

	# of Patients	Baseline AHI	Compliance Rate	Mean Nightly Usage
Stern, Cureus, 2021	28	21.8	93.6 %	7.2 +/- 0.9 hours
Hu, JDSM, 2018	8	37.2	87.9 %	7.4 +/- 1.4 hours

These studies demonstrate a high level of compliance at 93.6% and 87.9%, and mean nightly usage of 7.2 and 7.4 hours per night, with ProSomnus precision devices. For context, based on published literature we estimate the compliance rates for CPAP devices to be between 35% and 65%, and mean nightly use of approximately 4.5 hours. We believe that ProSomnus precision intraoral devices are the only devices that have demonstrated, in multiple studies using objectively recorded data, mean nightly use that meets or exceeds the AASM and AADSM recommended 7 hours of mean nightly usage.

Side Effects

Two studies, both independent, evaluated patients treated with ProSomnus precision intraoral devices for tooth position and bite changes for a minimum duration of 2 years. Tooth position and bite changes are dental oriented side effects commonly associated with CPAP and legacy dental products. The table below provides the key highlights from these studies.

	UoP	India Study
# of ProSomnus Therapy Patients	18	10
Mean Follow Up Duration	2.3 years	2.0 years
Tooth Position Changes Statistically Significant?	No	No
Bite Changes Statistically Significant?	No	No

In both studies, ProSomnus precision intraoral devices did not demonstrate the types of unwanted tooth movements and unwanted bite changes that have been reported in the literature with CPAP and legacy dental products. None of the tooth movements and bite changes were calculated as being statistically significant.

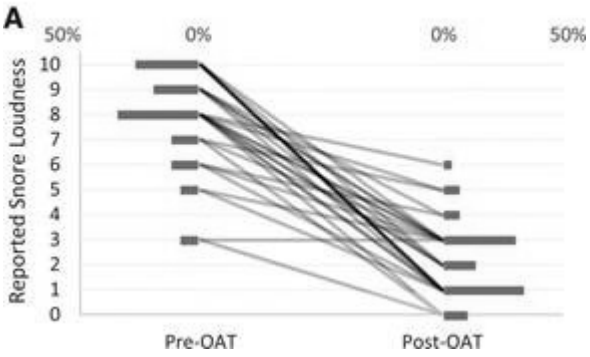
Patient Preference

The American Academy of Sleep Medicine notes that it is important for healthcare providers to consider patient preference when selecting a treatment modality, "…patient preference for OAs (oral appliances) versus CPAP should be considered by the treating sleep physician before therapy is prescribed." Elliott et al conducted a 31-patient preference study with the scientific abstract published in the journal, Sleep, in 2021. Their study intercepted 31 patients in treatment with CPAP or traditional oral appliances and converted them to ProSomnus precision devices. 100% of patients stated that they preferred the ProSomnus precision devices to their prior device.

Snoring

ProSomnus therapy is indicated by the FDA for the treatment of snoring. At six-month follow-up, 96.7% of participants in the independent NOTUS3 study reported a median improvement in snoring of 6 levels on a 10-point scale. See table below. The EFFECTS study utilized the Snore Severity Score ("SSS"), and reported a statistically significant improvement in snoring when the patients were treated with ProSomnus precision devices.

Figure 5—Symptom resolution.



Sales and Marketing

We sell our ProSomnus intraoral devices through a direct sales force that primarily targets sleep dentists, sleep physicians, primary care providers, otolarygologists (ENTs), and other integrated healthcare service providers. We have an established provider network across the United States. ProSomnus devices are authorized by the United States Department of Defense and US Army for the treatment of service men and woman who have OSA. We are currently initiating the marketing and sales of our ProSomnus intraoral devices in several European countries and intend to further expand our marketing and direct sales into international markets.

The AASM practice guidelines specify dentists with OSA training as the primary channel for delivering and managing intraoral appliance therapy for patients with OSA. Dentists can further specialize in sleep medicine by obtaining a credential of Diplomate from the American Board of Dental Sleep Medicine (ABDSM).

ABDSM diplomates are sleep trained dentists who have demonstrated competency in sleep medicine and who must actively engage in continuing education to maintain their credential. We estimate that approximately 6,000 dentists in the United States practice dental sleep medicine, a key call point for our sales and marketing efforts.

We currently have twelve direct sales representatives in the North America and four in Europe, for a total of sixteen direct sales representatives. We project increasing our count of direct sales representative to eighty over the forecast horizon. Increasing the count of direct sales representatives is one of the main growth drivers for our revenue projections. We seek to recruit sales representatives with strong direct sales backgrounds, experience in the dental or respiratory medicine markets, and core knowledge of medical device coding, medical affairs, and reimbursement. We believe there is a robust talent pool of sales professionals with relevant skills and experience. Our expectations for sales representative productivity are largely based on the historical performance of our sales representatives, management experience, and data available for comparable medical device companies with direct sales representatives. We anticipate normal variability in the performance of our sales representatives relative to our productivity expectations. Variability is largely driven by the performance of each representative, but also other factors such as the timing of when each representative is hired within a period.

Our company has put into place several programs to increase the probability of each representative achieving productivity expectations. These programs, which are continuously updated, include:

- Marketing, to increase customer awareness, strengthen our brand, and generate leads.
- Medical Affairs, to provide each representative with clinical data about our devices.
- OSA Training, to ensure that each representative has a basic understanding of the disease.
- Clinical Training, to ensure that each representative understands key clinical processes.
- Product Training, to ensure that each representative understands our devices and technology.

- Regulatory Training, to ensure each representative conforms with required regulations.
- Sales Systems, to provide our representatives with tools to effectively manage their territory.
- Commission Programs, to incentivize performance and de-risk underperformance.

We also utilize direct communication channels to inform and educate patients about ProSomnus intraoral devices and to enable them to connect with active qualified sleep dentists that offer our intraoral devices. Our primary methods of patient, physician and dentist outreach are search engine marketing, social media advertising, medical and dental journal advertising, trade shows and clinical education and in-office engagement of dentists and physicians. The objective of this outreach is to raise awareness of OSA and make it easy for at risk people to access care by using our website to read educational materials and find a list of providers in their area.

We utilize a five-stage prescription decision process to organize our sales and marketing efforts for the purpose of optimizing demand for our devices. This process is largely based upon a tried-and-true understanding of how healthcare providers select medical devices. The five stages to our process are: 1. Problem/opportunity awareness; 2. Information search; 3. Evaluation of options; 4. Prescription decision; and 5. Post-prescription activity.

The objective of the first stage, Problem/opportunity awareness, is to make the healthcare provider aware that our devices might help them to address problems or opportunities for their patients with OSA. This is largely accomplished through clinical education programming, ranging from sponsoring a conference such as the AASM or AADSM annual meetings to advertising in relevant medical journals. Healthcare providers that respond to our awareness programming are considered leads.

The objective of the second stage of our process, Information search, is to make it easy for healthcare providers, particularly the leads from our Problem/opportunity stage, to find information about our devices. We accomplish this by providing copies of relevant journal articles, references of healthcare providers who are already prescribing our devices, or sponsoring speakers at conferences.

Evaluation of options is the third stage of our marketing and sales process. The objective for this stage is to help healthcare providers make rational and conscious comparisons between our devices and competitive alternatives. This stage of the process largely involves a sales representative providing a healthcare provider with white papers, studies, journal articles, scientific abstracts, specifications and other technical details about our devices.

The fourth stage of our process is Prescription decision. The objective of the Prescription decision stage is to facilitate a trial order from the healthcare provider. Programming for this stage focuses on preparing the healthcare provider to prescribe a ProSomnus device in the form of pricing agreements, in-servicing, providing prescription pads, instructions for use, and other documents necessary to prescribe a device.

Post-prescription activity is the fifth stage of our prescription decision marketing and sales process. This stage involves a sales representative conducting post-prescription surveillance regarding any previously prescribed devices.

Third Party Reimbursement

We typically sell our ProSomnus intraoral devices to sleep dentists. These customers in turn bill various third-party payors, such as commercial payors, Medicare and the various social health plans of various countries around the world, for the cost of the device. The list price for each product is based upon an analysis of competitive prices, capacity dynamics, marginal manufacturing costs, incremental value created to the customer and our business strategy. We offer a quarterly volume based discount program, as well as incentives for new customers.

In the United States third-party payors require physicians and dentists to identify the service for which they are seeking reimbursement by using Current Procedural Terminology (CPT) codes, which are created and maintained by the American Medical Association (AMA). Our ProSomnus precision intraoral medical devices can be billed in and out of network to most commercial payors under the E0486 or K1027 CPT codes. The devices under CPT codes E0486 and K1027 are reimbursable by many major commercial medical payors following a medical diagnosis of OSA. Dentists and other healthcare providers are typically reimbursed by private medical insurance in the range of approximately $2,000 to $3,500 per patient for intraoral appliance therapy, although medical insurance is never a guarantee of payment, and patient deductibles and policy limitations may vary. Preauthorization may be required for reimbursement and preauthorization requirements may vary based on the payor 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 using our ProSomnus intraoral medical devices. Commercial medical insurance policies have different reimbursement policies which may affect availability of reimbursement.

Dentists typically remain out of network with commercial health insurance payors, but this depends on the individual practice and the commercial payor 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 AMA provides 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.

ProSomnus intraoral medical devices under the E0486 and K1027 HCPCS codes are reimbursable by Medicare or Medicaid. Physician reimbursement under Medicare generally is based on a defined fee schedule, the Physician Fee Schedule, through which payment amounts are determined by the relative values of the professional service rendered. Dentists and other healthcare providers are typically reimbursed by Medicare in the range of approximately $1,250 to $1,800 per patient for intraoral appliance therapy. The average amount varies by Medicare jurisdiction.

Manufacturing and Supply

We have developed a proprietary digital precision manufacturing platform that enables us to produce intraoral medical devices with greater speed, better precision and increased personalization parameters at lower cost points than our competitors' intraoral appliances. After a sleep dentist takes an impression of the patient's teeth using an intraoral scanner or other device, they send it to us along with a prescription. We then use our proprietary, artificial intelligence-driven software to create a custom design for the intraoral device using the digitized patient information and the dentist's prescription. Once the design is complete, we use computer-assisted manufacturing and a robotic milling machine to fabricate the device from medical grade (USP Class VI compliant) polymer. The device is then labeled, polished, packaged and sent to the dentist for delivery to the patient.

Our quality system is required to be in compliance with the Quality System regulations enforced by the FDA, and similar regulations enforced by other worldwide regulatory authorities. We have a formal, documented quality system by which quality objectives are defined, understood and achieved. Systems, processes and procedures are implemented to ensure high levels of product and service quality. We monitor the effectiveness of the quality system based on internal data and direct customer feedback and strive to continually improve our systems and processes, taking corrective action, as needed.

Since the manufacturing process of our products requires substantial and varied technical expertise, we believe that our manufacturing capabilities are important to our success. In order to produce our highly customized, highly precise intraoral medical devices in volume, we have developed a number of proprietary processes and technologies. These technologies include complex software algorithms and solutions, artificial intelligence, and the highest quality medical grade materials. To increase the efficiency of our manufacturing processes, we continue to focus our efforts on software development and the improvement of rate-limiting processes. We continuously upgrade our proprietary, three-dimensional treatment planning software to enhance computer analysis of treatment data and to reduce time spent on manual and judgmental tasks for each case, thereby increasing the efficiency of our technicians. In addition, to improve efficiency and increase the scale of our operations, we continue to invest in the development of automated systems for the fabrication and packaging of our intraoral devices.

Research and Development

We are committed to investing in world-class technology development, which we believe is critical to achieving our goal of establishing our ProSomnus intraoral devices as the standard method for treating OSA. Our research and development expenses were $3.0 million and $1.9 million for the years ended December 31, 2022 and 2021, respectively.

Our research and development activities are directed toward developing the technology innovations that we believe will deliver our next generation of products and platforms. These activities range from accelerating product and clinical innovation to developing manufacturing process improvements to researching future technologies and products. We received FDA clearance for an intraoral device that enables remote patient monitoring services in November 2020. We believe that these services could provide us with an additional recurring revenue stream.

Competition

Our industry is subject to significant competition and rapid change from the introduction of new products and technologies and other activities of industry participants. We currently compete as a first-line therapy in the OSA treatment market for patients with mild to moderate OSA. We intend to also compete as a first-line therapy for patients with severe OSA if we receive clearance from the FDA to do so. There are several treatment options for patients with OSA depending on the level of severity of the disease, ranging from lifestyle changes to surgery. The goals of therapy are to resolve signs and symptoms of OSA, improve sleep quality, normalize and reduce the AHI, and generally increase blood oxygen saturation levels.

We consider our primary competition to be manufacturers and providers of both CPAP and legacy intraoral appliance products. Providers of CPAP devices include ResMed, Philips Respironics and Fisher & Paykel. These companies are focused on CPAP devices,

with efforts to increase the rate of diagnosis worldwide. To address adherence issues, these companies are focused on home monitoring technologies.

Legacy dental products (most of which represent variations on the same mandibular advancement device platform) are typically delivered by licensed dentists and are usually fabricated in a dental laboratory. According to the American Sleep Apnea Association, over 100 different intraoral appliances are FDA cleared for the treatment of snoring and OSA. Manufacturers include SomnoMed, DynaFlex, and Respire.

We believe other emerging businesses are in the early stages of developing other intraoral appliance devices which incorporate novel technologies.

We may also compete with makers of surgically implanted upper airway stimulation devices for the treatment of OSA, including Inspire Medical (Inspire).

Some of our competitors have more financial resources than we do, while others have a more diversified set of products and end markets. Accordingly, such competitors may be able to more quickly respond to innovations, changes in patient demand, and market developments, and to better withstand external economic or market factors.

Intellectual Property

We rely on a combination of patent, copyright, trademark and trade secret laws and confidentiality agreements to protect our intellectual property rights, including entering into invention assignment agreements with our employees in the ordinary course of their employment. As of March 17, 2023, we have rights to: nine (9) issued U.S. utility patents, which will expire between Dec. 24, 2034, and Oct. 23, 2038, assuming all required fees are paid; one (1) issued U.S. design patent; three (3) pending U.S. patent applications, six (6) issued and active foreign patents and ten (10) pending foreign and WIPO-PCT patent applications.

We also rely, in part, upon unpatented trade secrets, know-how and continuing technological innovation, and may in the future rely upon licensing opportunities to develop and maintain our competitive position. We protect our proprietary rights through a variety of methods, including confidentiality and assignment agreements with suppliers, employees, consultants and others who may have access to our proprietary information.

There is no active patent litigation involving any of our patents and we have not received any notices of patent infringement. Our industry faces claims of infringement and litigation regarding patent and other intellectual property rights. Patent infringement is an ongoing risk, in part because other companies in our industry could have patent rights that may not be identifiable as we develop our products and services. Litigation may be necessary to enforce our intellectual property rights, and we may have to defend ourselves against infringement claims

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 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.

Our company markets and manufacturers Class II, FDA-cleared, medical devices. Our MicrO2 medical device has a 510(k) clearance as a Class II medical device with the FDA for the treatment of mild to moderate OSA and snoring. Our CA medical device has a 510(k) clearance as a Class II medical device with the FDA for the treatment of mild to moderate OSA and snoring. Our MicrO2 and CA 510(k) clearances include options for the provider to add Micro-recorders for the purpose of monitoring patient compliance. Our EVO has a 510(k) clearance as a Class II medical device with the FDA for the treatment of mild to moderate OSA and snoring. This device also has a 510(k) clearance as a Class II medical device with the FDA for the treatment of mild to moderate OSA and snoring with Patient Monitoring technology to monitor the performance of the device and the health of the patient.

Our FDA 510(k) clearances are summarized in the table below.

			Indications for Use	
Device Name	**FDA 510(k) #**	**Decision Date**	**OSA**	**Snoring**
MicrO2 OSA Device	K133683	7/24/14	Yes	Yes
MicrO2 OSA Device with Micro-Recorder	K161624	11/7/16	Yes	Yes
ProSomnus CA Sleep and Snore Device; ProSomnus CA Sleep and Snore Device with Micro-Recorder	K172859	11/22/17	Yes	Yes
ProSomnus EVO Sleep and Snore Device; ProSomnus EVO Sleep and Snore Device with Patient Monitoring	K202529	11/20/20	Yes	Yes
ProSomnus EVO PH Sleep and Snore Device	K221889	10/6/2022	Yes	Yes

We are currently engaged with the FDA in a process to determine the safety and efficacy of our ProSomnus precision intraoral devices for the treatment of severe OSA, as an additional expanded indication for use. We intend to apply for a 510(k) clearance for this expanded indication upon completion of our clinical study.

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 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 revenue. Any potential consequences of off-label use of our intraoral devices are the responsibility of the treating dentist; however, we may face consequences related to such off-label use.

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 27 Member States of the European Union ("**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 (the "Medical Devices Directive" or "**MMD**"). There is also a directive specifically addressing Active Implantable Medical Devices (Directive 90/385/EEC) (the "Active Implantable Medical Devices Directive" or "**AIMDD**"). 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 available in the EU. 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 MDD, 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 organizations designated by an EU country to assess the conformity of certain products before being placed on the market. These bodies carry out tasks related to conformity assessment procedures set out in the legislation and 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 MDD, Annex 7 to the AIMDD, and applicable European and International

Organization for Standardization ("ISO") standards, as implemented or adopted in the EEA Member States. Clinical investigations 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 May 25, 2017, the new Medical Devices Regulation (2017/745 or "MDR") entered into force, which repeals and replaces the EU MDD and AIMDD. Unlike directives, which must be implemented into the national laws of the EEA Member States, regulations are 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 MDR, 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 MDR was due to become applicable in May 2021, but in light of COVID-19, on April 23, 2020, the European Parliament and the Council of the EU adopted a proposal to extend the transitional period of the MDR by one year, i.e. until May 26, 2021. However, devices lawfully placed on the market pursuant to the MDD or AIMDD prior to May 26, 2021 may generally continue to be made available on the market or put into service until May 26, 2025. 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
- address 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.

Following the end of the "Brexit" Transition Period, from January 1, 2021 onwards, the Medicines and Healthcare Products Regulatory Agency ("MHRA") will be responsible for the UK medical device market. The new regulations will require medical devices to be registered with the agency (but manufacturers will be given a grace period of four to 12 months to comply with the new registration process). Manufacturers based outside the UK will need to appoint a UK Responsible Person to register devices with the MHRA in line with the grace periods. By July 1, 2023, in the UK (England, Scotland, and Wales), all medical devices will require a UKCA (UK Conformity Assessed) mark but CE marks issued by EU notified bodies will remain valid until this period. However, UKCA marking alone will not be recognized in the EU. The rules for placing medical devices on the Northern Ireland market will differ from those in the UK.

Similarly, 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; and
- necessity of testing performed in country by distributors for licensees.

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.

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.

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. 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 qualify for 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. Conduct and business arrangements that do not fully satisfy one of these safe harbor provisions may result in increased scrutiny by government enforcement authorities. 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.

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.

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.

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. 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.

The Civil Monetary Penalty Law 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.

The Health Insurance Portability and Accountability Act of 1996 ("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 specific EEA Member State legislation governing the advertising and promotion of medical devices. These laws, which vary between jurisdictions (thus making compliance more complex), 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. Many EEA Member States have adopted specific anti-gift statutes that further limit commercial practices for our products, in particular vis- à-vis healthcare professionals and organizations. 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 CHIP for payments and other transfers of value provided by them, directly or indirectly, to physicians, as defined by statute, certain other healthcare providers beginning in 2022, and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Manufacturers must submit reports by the 90th day of each calendar year. Many EU Member States have adopted national "Sunshine Acts" which impose similar reporting and transparency requirements (often on an annual basis) on certain drug, biologics and medical device manufacturers. 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.

Violation of any of the federal and state healthcare laws described above or any other governmental regulations that apply to device manufacturers may result in significant penalties, including the imposition of significant civil, criminal and administrative penalties, damages, disgorgement, monetary fines, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and/or oversight if the entity becomes subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and curtailment of operations.

Data Privacy and Security Laws

We are also subject to various federal, state, and foreign laws that protect personal information including certain patient health information, such as the EU General Data Protection Regulation ("**GDPR**") and the California Consumer Privacy Act ("**CCPA**") which became effective as of January 2020, 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 ("**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 PHI by covered entities as well as business associates, which are defined to include subcontractors that create, receive, maintain, or transmit PHI on behalf of a business associate. They also set forth certain rights that an individual has with respect to his or her PHI maintained by a covered entity, including the right to access or amend certain records containing PHI, or to request restrictions on the use or disclosure of PHI. The security regulations establish requirements for safeguarding the confidentiality, integrity, and availability of PHI 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 PHI 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 PHI or insofar as such state laws apply to personal information that is broader in scope than PHI as defined under HIPAA.

HIPAA requires the notification of patients, and other compliance actions, in the event of a breach of unsecured 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 the U.S. Department of Health and Human Services ("HHS") 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 significant civil monetary penalties and criminal penalties.

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 HHS conduct periodic compliance audits of HIPAA covered entities, and their business associates for compliance with the HIPAA privacy and security standards. It also tasks HHS 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 addition, California enacted the CCPA, effective January 1, 2020, which, among other things, creates new data privacy obligations for covered companies and provides new privacy rights to California residents, including the right to opt out of certain disclosures of their information. The CCPA also creates a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. Although the law includes limited exceptions, including for "protected health information" maintained by a covered entity or business associate, it may regulate or impact our processing of personal information depending on the context. Further, the California Privacy Rights Act ("CPRA"), recently passed in California. The CPRA will impose additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt-outs for certain uses of sensitive data. It will also create a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the provisions will go into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required.

In the EU, the EEA and the United Kingdom we are subject to laws that restrict our collection, control, processing, and other use of personal data (i.e. data relating to an identifiable living individual) including the GDPR and the United Kingdom Data Protection Act 2018 (and any applicable national laws implementing the GDPR). We process personal data in relation to our operations, including clinical investigations. We process data of our employees, contractors, suppliers, distributors, service providers, and our customers, as well as patient or clinical investigation participants, including health and medical information of such participants. We need to ensure compliance with the GDPR (and any applicable national laws implementing the GDPR) in each EU and EEA jurisdiction where we are established or are otherwise subject to the GDPR (i.e., jurisdictions in which we are targeting or monitoring EU and EEA located individuals, or offering goods or services to EU located individuals. We also need to ensure compliance with the Data Protection Act 2018.

The GDPR imposes onerous accountability obligations including: maintaining a record of data processing; implementing policies and a privacy governance framework; disclosing to data subjects how their personal data is to be used; limiting retention of personal data; mandatory data breach notification requirements; and high standards for data controllers to demonstrate that they have obtained valid consent for certain data processing activities. In addition, the GDPR permits EU Member State derogations for certain matters and, accordingly, we are also subject to EU national laws relating to the processing of genetic data, biometric data, and health data. We have a robust program that we believe ensures compliance with these obligations. Fines for certain breaches of the GDPR are significant: up to the greater of EUR 20 million or 4% of total global annual turnover. In addition to the foregoing, a breach of the GDPR could result in regulatory investigations, reputational damage, orders to cease/ change our use of data, enforcement notices, as well potential civil claims including class action type litigation where individuals suffer harm.

We are also subject to GDPR requirements with respect to cross-border transfers of personal data out of the EU and we need to ensure that such transfers are legitimized by valid transfer solutions and/or derogations under the GDPR (where required), including by

entering into the EU Commission approved model contracts for the transfer of personal data to third countries (i.e., the standard contractual clauses). The law is also developing rapidly and, in July 2020, the Court of Justice of the EU limited how organizations could lawfully transfer personal data from the EEA to the United States. As such, there is a possibility that the standard contractual clauses may be invalidated as a compliant data transfer mechanism in the near future. In addition, following the end of the Transition Period, the UK has become a "third party" for the purposes of EU-to-UK personal data transfers. The significant implications of this are mitigated by the agreement of a 4-6 month grace period, during which time the EU Commission will consider whether to grant an adequacy decision which would continue to permit unrestricted EU-to-UK personal data transfers following the expiry of the grace period. We have enlisted the help of external advisors to implement a robust GDPR program that we believe achieves and maintains compliance with these obligations, but it is likely it will require us to expend additional capital and other resources for upcoming GDPR changes.

We depend on a number of third parties in relation to the operation of our business, a number of which process personal data on our behalf. With each new provider we perform security assessments and detailed due diligence, enter into contractual arrangements which require that they only process personal data according to our instructions, and which require that they have sufficient technical and organizational security measures in place. We have enlisted the help of external advisors to provide assistance in implementing these contractual arrangements with our existing providers. There is no assurance that these contractual measures and our own privacy and security-related safeguards will protect us from the risks associated with the third-party processing, storage, and transmission of such information. Any violation of data or security laws by our third party processors could have a material adverse effect on our business and result in the fines and penalties outlined above.

We are also subject to evolving EU privacy laws on cookies and e-marketing. The EU is in the process of replacing the E-Privacy Directive with a new set of rules in the form of a regulation, which will be directly applicable to all EU Member States. The draft E-Privacy Regulation imposes strict opt-in marketing rules with limited exceptions for business-to-business communications, alters rules on third-party cookies, web beacons, and similar technology and significantly increases fining powers to the same levels as the GDPR (i.e. the greater of 20 million Euros or 4% of total global annual revenue for certain breaches). The e-Privacy Regulation is still going through the European legislative process and commentators expect it to be agreed during 2021, after which a two-year transition period will follow before it is in force. We have enlisted the help of external advisors to implement a robust GDPR program that achieves and maintains compliance with these obligations, but it is likely it will require us to expend additional capital and other resources for upcoming GDPR changes.

Healthcare Reform

The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality or expanding access.

Current and future legislative proposals to further reform healthcare or reduce healthcare costs may limit coverage of or lower reimbursement for the procedures associated with the use of our products. The cost containment measures that payors and providers are instituting and the effect of any healthcare reform initiative implemented in the future could impact our revenue from the sale of our products.

The implementation of the Affordable Care Act in the United States, for example, has changed healthcare financing and delivery by both governmental and private insurers substantially, and affected medical device manufacturers significantly. The Affordable Care Act, among other things, provided incentives to programs that increase the federal government's comparative effectiveness research, and implemented payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians, and other providers to improve the coordination, quality, and efficiency of certain healthcare services through bundled payment models. Additionally, the Affordable Care Act expanded eligibility criteria for Medicaid programs and created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the Affordable Care Act. By way of example, the Tax Cuts and Jobs Acts was enacted, which, among other things, removes penalties for not complying with the individual mandate to carry health insurance, beginning in 2019. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, ruled that the Affordable Care Act's individual mandate to carry insurance coverage is a critical and inseverable feature of the Affordable Care Act, and therefore, because it was repealed as part of the Tax Cuts and Jobs Act, the remaining provisions of the Affordable Care Act are invalid as well. On December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court's decision that the individual mandate was unconstitutional but remanded the case back to the District Court to determine whether the remaining provisions of the Affordable Care Act are invalid as well. The U.S. Supreme Court is currently reviewing the case,

although it is unclear how the Supreme Court will rule. It is also unclear how other efforts, if any, to challenge, repeal or replace the Affordable Care Act will impact the Act or our business.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, the Budget Control Act of 2011, among other things, included reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2021, unless additional Congressional action is taken. Additionally, the American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

We expect additional state and federal healthcare reform measures to be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressure.

Anti-Bribery and Corruption Laws

Our U.S. operations are subject to the 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 through EU Member State laws and under the Organization for Economic Co-operation and Development's Convention on Combating Bribery of Foreign Public Officials in International Business Transactions.

Seasonality

Historically, ProSomnus has experienced seasonality in the first and fourth quarters. Revenues have been more robust in the fourth quarter and less robust in the first quarter, and we expect this trend to continue. Seasonality is largely attributable to patients in the United States who are actively managing their out-of-pocket expenses, which may be higher in the beginning of the year when patients are less likely to have met the annual deductibles for their private insurance policies, and lower toward the end of the year when patients are more likely to have met their annual deductibles.

Human Capital

As of December 31, 2022, we had 125 employees in North America and 4 in Europe. None of our employees is subject to a collective bargaining agreement or represented by a trade or labor union. We consider our relationship with our employees to be good. We believe that our turnover and productivity levels are at acceptable levels.

Corporate Information

We incorporated under the laws of the State of Delaware in March 2016. Our principal executive offices are located at 5675 Gibraltar Drive, Pleasanton, CA 94588, and our telephone number is (844) 537-5337. The company maintains a website at the following address: www.ProSomnus.com. The information on the Company's website is not incorporated by reference in this report. We make available on or through our website certain reports and amendments to those reports that we file with or furnish to the Securities and Exchange Commission ("SEC") in accordance with the Securities Exchange Act of 1934, as amended ("Exchange Act"). These include our Annual Reports on Form 10-K, our Quarterly Reports on Form 10-Q and our Current Reports on Form 8-K. We make this information available on our website free of charge as soon as reasonably practicable after we electronically file the information with, or furnish it to, the SEC. In addition, we routinely post on the "Investors" page of our website news releases, announcements and other statements about our business and results of operations, some of which may contain information that may be deemed material to investors. Therefore, we encourage investors to monitor the "Investors" page of our website and review the information we post on that page.

The SEC maintains a website that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC at the following address: http://www.sec.gov.

Item 1A. Risk Factors

You should carefully consider all of the risks described below, together with the other information contained in this report, including the financial statements, before making a decision to invest in our securities. If any of the following risks occur, our business, financial condition or operating results may be materially and adversely affected. In that event, the trading price of our securities could decline, and you could lose all or part of your investment.

Risks Related to ProSomnus's Business and Industry

Our business has a limited operating history, which may make it difficult to evaluate the prospects for our future viability and predict our future performance. As such, you cannot rely upon our historical operating performance to make an investment or voting decision regarding ProSomnus.

ProSomnus, Inc. (formerly known as ProSomnus Holdings, Inc., DTI Holdings Inc. and MicroDental Inc.) was incorporated in 2006, for most of its history, its primary business was the operation of a chain of dental laboratories. In October 2016, it sold the dental laboratory business and retained the sleep apnea business it started in 2014, and formed ProSomnus Sleep Technologies, Inc. as a wholly owned subsidiary to operate that business. Accordingly, we have a limited operating history and must be evaluated in light of the uncertainties, risks, expenses, and difficulties frequently encountered by companies in their early stages of operations.

In addition, as a business with a limited operating history, we may encounter unforeseen expenses, difficulties, complications, delays, and other known and unknown obstacles. We have encountered in the past, and will encounter in the future, risks and uncertainties frequently experienced by growing companies with limited operating histories in emerging and rapidly changing industries. If our assumptions regarding these risks and uncertainties, which we use to plan and operate our business, are incorrect or change, or if we do not address these risks successfully, our results of operations could differ materially from our expectations, and our business, financial condition, and results of operations could be adversely affected.

We have a history of operating losses and may never achieve cash flow positive or profitable results of operations.

Since we began our ProSomnus business in 2016, we have not been profitable and have incurred losses and cash flow deficits. For the fiscal years ended December 31, 2022 and 2021, we reported net losses of $7.1 million and $6.0 million, respectively, and negative cash flow from operating activities of $10.3 million and $4.6 million, respectively. Accumulated deficit as of December 31, 2022 was $210.8 million.

We anticipate that we will continue to report losses and negative cash flow. There is therefore a risk that we will be unable to operate our business in a manner that generates positive cash flow or profit, and our failure to operate our business profitably could damage our reputation and stock price.

Based on cash flow projections from operating and financing activities and existing balance of cash and cash equivalents and investments, management is of the opinion that the Company has sufficient funds for sustainable operations, and it will be able to meet its payment obligations from operations and debt related commitments for at least one year from the issuance date of these financial statements.

The Company's ability to continue as a going concern is dependent on management's ability to control operating costs and maintain revenue growth forecast. However, additional funding will be necessary to fund future discovery research, pre-clinical and clinical activities. We will seek additional funding through public financings, debt financings, collaboration agreements, strategic alliances and licensing arrangements. Although we have been successful in raising capital in the past, there is no assurance that we will be successful in obtaining such additional financing on acceptable terms, or at all, and we may not be able to enter into collaborations or other arrangements. If we are unable to obtain funding, we could be forced to delay, reduce or eliminate our research and development programs, product portfolio expansion or commercialization efforts, which could adversely affect our business prospects, and even our ability to continue operations.

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

In connection with the audit of our consolidated financial statements for the years ended December 31, 2022 and 2021, our independent registered public accounting firms 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. The material weakness in our case arose from the accounting for certain complex transactions and a lack of expertise for such accounting issues. While remediation efforts have been made, if we are unable to remedy our material weakness, 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 will not be successful if our ProSomnus precision intraoral medical devices are not sufficiently adopted by the medical and dental communities for the treatment of Obstructive Sleep Apnea (OSA).

Our success depends both on the sufficient acceptance and adoption by the dental and medical communities of our ProSomnus precision intraoral medical devices as a non-invasive treatment for the treatment of mild to moderate OSA and potentially severe OSA in the future and on heightening public awareness of the prevalence of OSA to increase the number of undiagnosed patients who seek treatment. Currently, a relatively limited number of dentists and other medical professionals provide ProSomnus precision intraoral medical devices for the treatment of OSA. We cannot predict how quickly, if at all, the medical and dental communities will accept our precision intraoral medical devices, or, if accepted, the extent of their use.

For us to be successful:

- our dentist customers and referring physicians must believe that the ProSomnus precision intraoral medical devices offer 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 OSA, and referring physicians must write a prescription for the use of ProSomnus precision intraoral medical devices;

- our dentist customers must use ProSomnus precision intraoral medical devices to treat OSA either as a stand-alone treatment or in combination with procedures to treat other areas of upper airway obstruction and achieve acceptable clinical outcomes in the patients they treat;

- our dentist customers must believe patients will pay for ProSomnus precision intraoral medical devices out-of-pocket or have qualifying medical insurance, and patients must believe that paying out-of-pocket or using their medical insurance for treatment is the best alternative to either doing nothing or entering into another treatment option; and

- our dentist customers must be willing to commit the time and resources required to learn the new clinical and technical skills required to treat patients with OSA using ProSomnus precision intraoral medical devices.

Studies have shown that a significant percentage of people who have OSA remain undiagnosed and therefore do not seek treatment, or those who are diagnosed with OSA may be reluctant to seek treatment or incur significant costs of treatment given the less severe nature of their condition, the potentially negative lifestyle effects of Continuous Positive Airway Pressure (CPAP) and other traditional treatments, and the lack of awareness of new treatment options. If there is not an increase in public awareness of the prevalence of OSA or if the medical and dental communities are slow to adopt, or fail to adopt, ProSomnus precision intraoral medical devices as a treatment for individuals with OSA, we would suffer a material adverse effect on our business, financial condition, and results of operations.

We derive a substantial portion of our revenue from sales of a single type of product (ProSomnus precision intraoral medical devices) and expect to continue to do so, which leaves us reliant on the commercial viability of the ProSomnus precision intraoral medical devices.

Currently, our only products are ProSomnus precision intraoral medical devices. We expect a secondary source of revenue to be remote monitoring services, which we expect to introduce soon. We expect that sales of our ProSomnus precision intraoral medical devices will account for a significant amount of our revenue for the foreseeable future. We currently market and sell our ProSomnus precision intraoral medical devices primarily in the United States and Canada, with a very limited presence in very few select European countries and Australia. Because the ProSomnus precision intraoral medical devices are different from current surgical and non-surgical treatments for OSA, we cannot assure you that dentists in corroboration with physicians will use our products, and demand for our products may decline or may not increase as quickly as we expect. Also, we cannot assure you that the ProSomnus precision intraoral medical devices will compete effectively as a treatment alternative to other more well-known and well-established therapies, such as CPAP, palatal surgical procedures, or other oral appliance therapy devices.

Since our ProSomnus precision intraoral medical devices currently represent our only products, we are significantly reliant on the level of recurring sales of the ProSomnus precision intraoral medical devices and decreased or lower than expected sales or recruitment of physicians and sleep dentists to recommend our products would have a material adverse effect on our business, financial condition, and results of operations.

We expect to introduce remote monitoring services soon. We may be unable to launch these new services on time, at all, or without significant additional expense, and such services may not be as popular as we anticipated, which would have a material adverse effect on our business, financial condition, and results of operations.

We face risks relating to public health conditions such as the COVID-19 pandemic, which could adversely affect our dentist customers, sleep physicians, 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 the emergence of the Omicron variant in the United States in December 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 and limit patient visits to sleep dentists and physicians. 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 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 timely procure required materials. The effects of the COVID-19 pandemic have also placed travel restrictions on us, as well as temporary closures of the facilities of our suppliers 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 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 by successfully attracting sleep dentists and sleep physicians on a timely basis or at all, which could harm our business, financial condition, and results of operations.

The growth of our business depends on our ability to execute our plan to attract new sleep dentists and sleep physicians. Our ability to recruit sleep dentists and sleep physicians depends on many factors, including our ability to:

- achieve brand awareness in new and existing markets;
- convince sleep dentists and sleep physicians of the value of our products and services and to make the required investments in becoming a provider of ProSomnus precision intraoral medical devices;
- 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 our precision intraoral medical devices and remote monitoring services and for services rendered at dental or physician offices relating to our precision intraoral medical devices;
- develop new products and services;
- expand to new markets;
- 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 sleep dentists that provide our devices to their patients.

Accordingly, we may not be able to achieve our planned growth or, even if we are able to grow our base of sleep dentists as planned, we may not be profitable or otherwise perform as planned. We may also struggle to recruit and train ProSomnus employees which could limit our ability to deliver product in a timely manner. Failure to successfully implement our growth strategy would likely have an adverse impact on our business, financial condition, and results of operations.

Our sales and marketing efforts may not be successful.

We currently market and sell our ProSomnus precision intraoral medical devices to a limited number of licensed professionals, primarily sleep dentists. Approximately 2.4% of dentists in the United States have been trained in providing our ProSomnus precision intraoral medical devices. The commercial success of our ProSomnus precision intraoral medical devices ultimately depends upon a number of factors, including the number of sleep dentists who provide our ProSomnus precision intraoral medical devices to their patients, the number of devices provided by these dentists, the number of patients who become aware of our ProSomnus precision intraoral medical devices by self-referral or referrals by their primary care or sleep physicians, the number of patients who elect to use our ProSomnus precision intraoral medical devices, and the number of patients who, having successfully used our ProSomnus precision intraoral medical devices, endorse and refer our ProSomnus precision intraoral medical devices to other potential patients..

Although we sell our products directly to sleep dentists, our experience in marketing and selling our ProSomnus precision intraoral medical devices 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 internationally or train a suitable number of sleep dentists and physicians. Our marketing and sales efforts may not be successful in increasing awareness and sales of our ProSomnus precision intraoral medical devices.

The failure to educate or train a sufficient number of physicians and dentists in the use of our ProSomnus precision intraoral medical devices could reduce the market acceptance of our ProSomnus precision intraoral medical devices and reduce our revenue.

It is critical to the success of our sales efforts that there is an increasing number of sleep dentists and sleep physicians familiar with, trained in, and proficient in the use of our ProSomnus precision intraoral medical devices. Currently, sleep dentists learn to use our ProSomnus precision intraoral medical devices through hands-on, on-site training or virtual training by our representatives. However, to receive this training, dentists must be aware of our ProSomnus precision intraoral medical devices as a treatment option for OSA and be interested in using our ProSomnus precision intraoral medical devices 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 ProSomnus precision intraoral medical devices, have the knowledge of or experience in the clinical outcomes of our ProSomnus precision intraoral medical devices, or feel comfortable enough using our ProSomnus precision intraoral medical devices to recommend it to their patients. Even if a dentist is well versed in our ProSomnus precision intraoral medical devices, he or she may be unwilling to require patients to pay for the oral device out-of-pocket if not covered by medical insurance. If dentists do not continue to accept and recommend our ProSomnus precision intraoral medical devices, our revenue could be materially and adversely affected.

Our marketing activities may not be successful.

We incur costs and expend other resources in our marketing efforts to attract and retain sleep dentists, referring physicians and patients. Our marketing activities are principally focused on increasing brand awareness in the communities in which we provide services. We expect to undertake marketing campaigns to increase awareness about our presence and our service capabilities. If we are not successful in these efforts, we will have incurred expenses without materially increasing revenue.

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 our ProSomnus precision intraoral medical devices**,** 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 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 our precision intraoral medical devices for the treatment of OSA by dentists, physicians, and patients;
- the success of alternative therapies and surgical procedures to treat individuals with OSA, and the possible future introduction of new products and treatments for OSA;
- our ability to maintain current pricing for our products;
- our ability to expand by recruiting additional sleep dentists and physicians in leading major metropolitan areas;
- the expansion and rate of success of our marketing and advertising efforts to patients, dentists and physicians, and the rate of success of our direct sales force in the United States and internationally;

- failure of suppliers to deliver machinery or raw materials or provide services in a cost effective and timely manner;
- our failure to develop, find, or market new products and/or services;
- 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 using our precision intraoral medical devices;
- actions relating to ongoing FDA compliance;
- the volume and timing of orders from dentists;
- our ability to obtain reimbursement for our ProSomnus precision intraoral medical devices and remote monitoring services for the treatment of OSA from third-party healthcare insurers;
- the willingness of patients to pay out-of-pocket for treatment using ProSomnus precision intraoral medical devices in the absence of reimbursement from third-party healthcare insurers for the treatment of OSA;
- decisions by one or more commercial health insurance companies to preclude, deny, limit, reduce, eliminate, or curtail reimbursement for treatment in whole or part by our precision intraoral medical devices precision intraoral medical devices;
- unanticipated delays in the development and introduction of our future products and services and/or our inability to control costs;
- the effects of global or local pandemics or epidemics, such as COVID-19, and resulting governmental responses;
- seasonal fluctuations in revenue due to the elective nature of sleep-disordered breathing treatments, including our ProSomnus precision intraoral medical devices, 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.

We may not be able to respond in a timely and cost-effective manner to changes in the preferences of physicians, dental sleep medicine providers or patients.

Our ProSomnus precision intraoral medical devices are subject to changing preferences of both physicians and dental sleep medicine providers that provide our precisions intraoral medical devices to patients and the patients themselves. A shift in preferences away from the precision intraoral medical devices we offer would result in our results of operations in future periods to be materially adversely impacted.

Further clinical studies of our ProSomnus precision intraoral medical devices may adversely impact our ability to generate revenue if they do not demonstrate that our devices are clinically effective for currently specified or expanded indications or if they are not completed in a timely manner.

We have conducted a number of clinical studies of the use of our ProSomnus precision intraoral medical devices to treat patients with mild to moderate OSA in the United States and Canada. We are also involved in a number of ongoing clinical studies evaluating clinical outcomes from the use of our ProSomnus precision intraoral medical devices, 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 our ProSomnus precision intraoral medical devices, including for the treatment of severe OSA.

We cannot assure you that these clinical studies will continue to demonstrate that our ProSomnus precision intraoral medical devices provide clinical effectiveness for individuals diagnosed with mild to moderate OSA or will demonstrate that such devices also provide clinical effectiveness for individuals diagnosed with severe OSA, nor can we assure you that the use of our ProSomnus precision intraoral medical devices 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 our ProSomnus precision intraoral medical devices 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 our ProSomnus precision intraoral medical devices for such expanded indications.

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 our ProSomnus precision intraoral medical devices 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 our ProSomnus precision intraoral medical devices achieve adequate levels of third-party insurance reimbursement.

The cost of treatments for OSA, such as CPAP, and most surgical procedures generally are covered and reimbursed in whole or part by third-party healthcare insurers. Our ProSomnus precision intraoral medical devices are customized oral appliances, most of which currently qualify for reimbursement for the treatment of mild to moderate OSA. Our ability to generate future revenue from additional sales of our ProSomnus precision intraoral medical devices and remote monitoring services for the treatment of OSA may be materially limited by the extent to which reimbursement of our ProSomnus precision intraoral medical devices and remote monitoring services for the treatment of OSA is available in the future. In addition, third-party healthcare insurers are increasingly challenging the prices charged for medical products and procedures. Any changes in this reimbursement system or reimbursement levels 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 our ProSomnus precision intraoral medical devices 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 our ProSomnus precision intraoral medical devices and potential revenue growth in the markets in which these approvals are sought.

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

The market for treating OSA, including sleep apnea in people of all ages, is highly competitive and evolving rapidly. We compete as a front-line therapy in the OSA treatment market for patients with mild to moderate OSA. According to the American Sleep Apnea Association, over 100 different oral appliances are FDA cleared for the treatment of snoring and obstructive sleep apnea. Our ProSomnus precision intraoral medical devices 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 of treating OSA and have established relationships with pulmonologists, sleep clinics, and ear, nose and throat specialists (ENTs), 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. We cannot predict the extent to which ENTs, oral maxillofacial surgeons, primary care physicians, or pulmonologists would or will recommend our ProSomnus precision intraoral medical devices over new or other established devices, treatments, or procedures.

Moreover, we are in the early stages of implementing our business plan and have historically had limited resources with which to market, develop and sell our ProSomnus precision intraoral medical devices. 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.

Our ProSomnus precision intraoral medical devices 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 OSA may render our ProSomnus precision intraoral medical devices 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 services to upgrade or improve our existing ProSomnus precisions intraoral medical devices to respond to a changing market before our competitors are able to do so, our ability to market our products and generate substantial revenue may be limited.

Our potential international sales are subject to a number of risks that could seriously harm our ability to successfully commercialize our ProSomnus precision intraoral medical devices in international markets.

We do not have any significant international sales outside of Canada, although we hope to more broadly introduce our ProSomnus precision intraoral medical devices into international markets in the future. Our ability to generate international sales is subject to several risks, including:

- our ability to recruit and train the appropriate staff;
- our ability to obtain appropriate regulatory approvals to market our ProSomnus precision intraoral medical devices in certain countries;
- our ability to identify sleep dentists and sleep physicians in international markets;
- 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 maintain supply relationships for certain of our key manufacturing systems and raw materials, and our business and operating results could be harmed if supply is restricted or ends or the price of raw materials used in our manufacturing process increases.

We are highly dependent on manufacturers of specialized oral scanning equipment, milling machines, and advanced medical grade raw materials for the fabrication of our precision intraoral medical devices. We maintain supply relationships for many of these systems and materials. We are also committed to purchasing the vast majority of our advanced medical grade Class VI polymer, the primary raw material used in our manufacturing of our precision intraoral medical devices, from a certain sources. While it is our goal to have multiple sources to procure certain key components, in some cases it may not be economically practical or feasible to do so. To mitigate this risk, we maintain an awareness of alternate supply sources that could provide our components with minimal or no modification to the current version of our precision intraoral medical devices, practice supply chain management, maintain safety stocks of critical components and have arrangements with our key vendors to manage the availability of critical components. If these or other suppliers encounter financial, operating, or other difficulties or if our relationship with them changes, we might not be able to quickly establish or qualify replacement sources of supply and could face production interruptions, delays, and inefficiencies. In addition, technological changes by our vendors could disrupt our manufacturing process or require expensive, time-consuming development efforts to adapt and integrate new equipment or processes. Our growth may exceed the capacity of one or more of these manufacturers to produce the needed equipment and materials in sufficient quantities to support our growth. Conversely, in order to secure supplies for production of our precision intraoral medical devices, we sometimes enter into non-cancelable purchase commitments with vendors, which could impact our ability to adjust our inventory to reflect declining market demands. If demand for our products is less than we expect, we may experience additional excess and obsolete inventories and be forced to incur additional charges and our profitability may suffer. In the event of technology changes, delivery delays, or shortages of or increases in price for these items, our business and growth prospects may be harmed.

The failure of dentists to pay for their purchases of our ProSomnus precision intraoral medical devices on a timely basis could reduce our future revenue and negatively impact our liquidity.

The timing and extent of our future growth in revenue depends, in part, on our ability to continue to increase the number of sleep dentists using our ProSomnus precision intraoral medical devices, as well as expanding the number of our ProSomnus precision intraoral medical devices used by these dentists. To the extent one or more of our large dentist customers fails to pay us for our ProSomnus

precision intraoral medical devices on a timely basis, we may be required to discontinue selling to these dentists and find new customers, which could reduce our future revenue and negatively impact our liquidity.

Our revenues may depend on our patients' and providers' receipt of adequate reimbursement from private insurers and government sponsored healthcare programs.

Political, economic, and regulatory influences continue to change the medical device industry in the United States. The ability of patients to pay fees for our devices will partially depend on the extent to which reimbursement for the costs of such materials and related treatments will continue to be available from private health coverage insurers and other similar organizations. We may have difficulty gaining market acceptance for the products we sell if third-party payors do not provide adequate coverage and reimbursement to physicians and care providers. Major third-party payors, such as private healthcare insurers, periodically revise their payment methodologies based, in part, upon changes in government sponsored healthcare programs. We cannot predict these periodic revisions with certainty, and such revisions may result in adverse changes to reimbursement for certain specified devices, potentially adversely impacting our business, results of operations, and financial conditions.

The sales of our devices will depend in part on the availability of reimbursement by third-party payors, such as government health administration authorities, private health insurers and other organizations. Third-party payors often challenge the price and cost-effectiveness of medical devices and services. Governmental approval of medical products does not guarantee that these third-party payors will pay for the products. Even if third-party payors do accept our medical devices, the amounts they pay may not be adequate to enable us to realize a profit. Legislation and regulations affecting the pricing of devices may change before our products and services are approved for marketing, and any such changes could further limit reimbursement, if any.

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 cleared or approved for commercial sale by the FDA and manufactured in facilities licensed and regulated by the FDA or an applicable foreign regulatory authority. Our ProSomnus precision intraoral medical devices are designed to affect, and any future products will be designed to affect, important bodily functions and processes. Any side effects, manufacturing defects, misuse, or abuse associated with our ProSomnus precision intraoral medical devices could potentially 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 our ProSomnus precision intraoral medical devices cause, or merely appear to have caused, patient injury or death. In addition, an injury that is caused by the activities of our suppliers, such as those who provide us with components and raw materials, 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 ProSomnus precision intraoral medical devices, 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 ProSomnus precision intraoral medical devices or new products;
- decreased demand and brand reputation for our ProSomnus precision intraoral medical devices;
- product recalls or withdrawals from the market;
- withdrawal of clinical trial participants;
- substantial monetary awards to patients or other claimants; or
- loss of revenue.

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.

We bear the risk of warranty claims on our ProSomnus precision intraoral medical devices.

We bear the risk of warranty claims on our ProSomnus precision intraoral medical devices. 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 or patients related to third-party components may arise after our ability to bring corresponding warranty claims against such suppliers expires, which could result in costs to us.

Risks Related to Intellectual Property

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 our ProSomnus precision intraoral medical devices and our manufacturing process and the confidentiality of proprietary technology. 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 any filed 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 United States, 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 ("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 products 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 technology. We depend heavily upon confidentiality agreements with our officers, employees, consultants, and subcontractors to maintain the proprietary nature of our technology. 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.

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, 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.

Risks Related to Government and Regulation

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 our ProSomnus precision intraoral medical devices are subject to extensive regulation for safety, efficacy, and quality by numerous government authorities in the United States and internationally. Before receiving FDA or foreign regulatory clearance to market our products which are not presently approved, we will have to demonstrate that these products are safe and effective in the patient population and for the indications 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 additional 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 could 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 United States 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 as, or substantially equivalent 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 and is 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 our ProSomnus precision intraoral medical devices 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 ("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.

Our ProSomnus precision intraoral medical device has received 510(k) Class II clearance from the FDA for treating mild to moderate OSA and snoring in adults.

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.

Although we are not currently subject to any FDA warning letters, censures or audits, 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.

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.

Our ProSomnus precision intraoral medical devices are subject to extensive governmental regulation that could prevent us from selling our ProSomnus precision intraoral medical devices or introducing new and/or improved products and services in the United States or internationally.

Our precision intraoral medical devices, manufacturing activities, and remote monitoring services are subject to extensive regulation by a number of 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 our ProSomnus precision intraoral medical devices; 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 may delay or prevent us from introducing any new models of our ProSomnus precision intraoral medical devices or other new products or services. In addition, government regulations may be adopted that could prevent, delay, modify, or rescind regulatory clearance or approval of our products.

Our manufacturing activities are further required to demonstrate compliance with the FDA's quality system regulations. The FDA enforces 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 relationships with dentists, 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 dentists), physicians, and third-party payors in the United States and elsewhere will play a primary role in the recommendation of our ProSomnus precision intraoral medical devices. 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 healthcare 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 purchasing, recommending, 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 ProSomnus precision intraoral medical devices 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 our ProSomnus precision intraoral medical devices for uses outside of the FDA-cleared indications for use, known as off-label uses. We cannot, however, prevent a dental or medical professional from using our ProSomnus precision intraoral medical devices 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 ProSomnus precision intraoral medical devices off-label. Furthermore, the use of our ProSomnus precision intraoral medical devices 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, certain sleep dentists may use our ProSomnus precision intraoral medical devices off-label, there is a risk that we could face regulatory scrutiny as a result of such use. If the FDA or any foreign

regulatory body determines that our promotional materials or training constitute promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance or imposition of 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 ProSomnus precision intraoral medical devices or use improper techniques if they are not adequately trained, potentially leading to injury and an increased risk of product liability. If our ProSomnus precision intraoral medical devices are misused or used with improper technique, we may become subject to costly litigation by our customers or their patients. 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 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 distribution of our products outside of 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 Securities

There can be no assurance we will be able to comply with the continued listing standards of Nasdaq for our Common Stock.

Our Common Stock and our Public Warrants are listed on the Nasdaq Global Market and Nasdaq Capital Market, respectively, under the symbols "OSA" and "OSAAW," respectively. In order to maintain such listing, we must satisfy minimum financial and other continued listing requirements and standards. In the event we fail to comply with the continued listing requirements of Nasdaq, we can provide no assurance that any action taken by us to restore compliance with listing requirements would prevent our Common Stock from dropping below the Nasdaq minimum bid price requirement, improve our stockholders' equity or otherwise prevent future non-compliance with Nasdaq's continued listing requirements. In such event, Nasdaq would delist our Common Stock. If our Common Stock or Warrants are subsequently delisted, it would likely have a negative effect on the price of such securities and would impair your ability to sell or purchase such securities when you wish to do so.

Concentration of ownership among ProSomnus's existing executive officers, directors and their affiliates may prevent new investors from influencing significant corporate decisions.

Our directors and executive officers and their affiliates as a group beneficially own approximately 7.8% of our outstanding Common Stock. As a result, these stockholders will be able to exercise a significant level of control over all matters requiring stockholder approval, including the election of directors, any amendment of our certificate of incorporation and any approval of significant corporate transactions. This control could have the effect of delaying or preventing a change of control or changes in management and will make the approval of certain transactions difficult or impossible without the support of these stockholders.

Sales of a substantial number of shares of our securities in the public market could cause the price of our securities to fall.

As of December 31, 2022, we had 16,041,464 outstanding shares of Common Stock. An additional 339,000 shares were reserved in Escrow. We had outstanding warrants to purchase 6,512,087 shares of our Common Stock. On March 17, 2023, the closing price on Nasdaq for our Common Stock was $5.17 and for our Public Warrants was $0.11.

These outstanding Warrants became exercisable on January 6, 2023, at an exercise price of $11.50 per share. In addition, 2,411,283 million shares of Common Stock will be available for future issuance under the 2022 Incentive Plan. To the extent such warrants are exercised, or we grant additional stock options or other stock-based awards under the 2022 Incentive Plan, additional shares of Common Stock will be issued, which will result in dilution to the holders of our Common Stock and increase the number of shares eligible for resale in the public market.

Furthermore, although the shares of Common Stock issued in the Business Combination are subject to lock-up restrictions, as described elsewhere in this annual report, upon the lapse of these lock-up restrictions, a substantial number of additional shares of Common Stock will become eligible for resale in the public market.

Sales of a substantial number of shares of Common Stock or warrants in the public market or the perception that these sales might occur could depress the market price of the Common Stock and/or warrants and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that sales may have on the prevailing market price of our Common Stock and warrants.

Pursuant to the registration rights agreement entered into in connection with the Business Combination and which is described elsewhere in this annual report, certain stockholders can demand that we register their registrable securities under certain circumstances and also have piggyback registration rights for these securities in connection with certain registrations of securities that we undertake. We have filed and intend to maintain an effective registration statement under the Securities Act covering such securities.

The registration of these securities will permit the public resale of such securities. The registration and availability of such a significant number of securities for trading in the public market may have an adverse effect on the market price of our securities post-Business Combination.

There is no guarantee that our Warrants will be in the money, and they may expire worthless.

The exercise price for our Warrants is $11.50 per share. The likelihood that the holders of the Warrants will exercise their Warrants, and therefore the amount of cash proceeds that we would receive, is dependent upon the market price of our Common Stock ,which is currently below the exercise price for our Warrants. If the market price of our Common Stock continues to be less than the exercise price, it is unlikely that holders will exercise the Warrants, and therefore unlikely that we will receive any proceeds from the exercise of these warrants and options in the near future, or at all.

Our amended and restated certificate of incorporation grants our board the power to issue additional shares of common and preferred stock and to designate series of preferred stock, all without stockholder approval.

As of December 31, 2022, we are authorized to issue 101,000,000 shares of capital stock, of which 1,000,000 shares will be authorized as preferred stock. Our board of directors, without any action by our stockholders, may designate and issue shares of preferred stock in such series as it deems appropriate and establish the rights, preferences and privileges of such shares, including dividends, liquidation and voting rights, provided it is consistent with Delaware law.

The rights of holders of our preferred stock that may be issued could be superior to the rights of holders of Common Stock. The designation and issuance of shares of capital stock having preferential rights could adversely affect other rights appurtenant to shares of the Common Stock. Further, any issuances of additional stock (common or preferred) will dilute the percentage of ownership interest of then current holders of our capital stock and may dilute the book value per share.

Neither ProSomnus nor Lakeshore has ever paid cash dividends on its capital stock, and we do not anticipate paying dividends in the foreseeable future.

Neither ProSomnus nor Lakeshore Acquisition I Corp. (“Lakeshore”) has ever paid cash dividends on any of its capital stock and we currently intend to retain any future earnings to fund the growth of our business. Any determination to pay dividends in the future will be at the discretion of our board of directors and will depend on our financial condition, operating results, capital requirements, general business conditions and other factors that the board may deem relevant. As a result, capital appreciation, if any, of our Common Stock will be the sole source of gain for the foreseeable future.

The trading price our securities is likely to be volatile, and you may not be able to sell our securities at or above the price you paid.

We expect the trading price of our Common Stock and Warrants to be volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors include:

- actual or anticipated fluctuations in operating results;
- failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;
- issuance of new or updated research or reports by securities analysts or changed recommendations for our stock or the industry in general;

- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- operating and share price performance of other companies that investors deem comparable to us;
- our focus on long-term goals over short-term results;
- the timing and magnitude of our investments in the growth of our business;
- actual or anticipated changes in laws and regulations affecting our business;
- additions or departures of key management or other personnel;
- disputes or other developments related to our intellectual property or other proprietary rights, including litigation;
- our ability to market new and enhanced products and technologies on a timely basis;
- sales of substantial amounts of the Common Stock by executive officers, directors or significant stockholders or the perception that such sales could occur;
- changes in our capital structure, including future issuances of securities or the incurrence of debt;
- the impact of the COVID-19 pandemic and the response of governments and business to the pandemic; and
- general economic, political and market conditions.

In addition, the stock market in general, and Nasdaq in particular, has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. Broad market and industry factors may seriously affect the market price of our securities, regardless of our actual operating performance. In addition, in the past, following periods of volatility in the overall market and the market price of a particular company's securities, securities class action litigation has often been instituted against these companies. This litigation, if instituted against us, could result in substantial costs and a diversion of our management's attention and resources.

If securities or industry analysts issue an adverse opinion regarding our Common Stock or do not publish research or reports about us, the price and trading volume of our securities could decline.

The trading market for our Common Stock and Warrants will depend in part on the research and reports that equity research analysts publish about us and our business. We do not control these analysts or the content and opinions included in their reports. Securities analysts may elect not to provide research coverage of our company and such lack of research coverage may adversely affect the market price of our Common Stock and Warrants. The price of our Common Stock and Warrants could also decline if one or more equity research analysts downgrade their recommendations with respect to our Common Stock and Warrants, change their price targets, issue other unfavorable commentary or cease publishing reports about us or our business. If one or more equity research analysts cease coverage of the company, we could lose visibility in the market, which in turn could cause the price of our securities to decline.

We may redeem your unexpired warrants prior to their exercise at a time that is disadvantageous to you, thereby making your warrants worthless.

We may redeem outstanding Warrants prior to their exercise at a time that is disadvantageous to you, thereby significantly impairing the value of such warrants. We will have the ability to redeem outstanding Warrants at any time after they become exercisable and prior to their expiration, at a price of $0.01 per warrant, provided that the closing price of Common Stock equals or exceeds $18.00 per share (as adjusted for share sub-divisions, share capitalizations, reorganizations, recapitalizations and the like) for any 20 trading days within a 30 trading day period ending on the third trading day prior to the date on which a notice of redemption is sent to the warrant holders. The Private Warrants have terms and provisions that are identical to those of the warrants sold as part of the LAAA Units, including with respect to redeemability.

We will not redeem the Warrants as described above unless a registration statement under the Securities Act covering the Common Stock issuable upon exercise of such Warrants is effective and a current prospectus relating to the Common Stock is available throughout the 30-day redemption period. If and when the Warrants become redeemable by us, we may exercise our redemption right even if we

are unable to register or qualify the underlying securities for sale under all applicable state securities laws. Redemption of the outstanding Warrants could force you (i) to exercise your Warrants and pay the exercise price therefor at a time when it may be disadvantageous for you to do so, (ii) to sell your Warrants at the then-current market price when you might otherwise wish to hold your Warrants, or (iii) to accept the nominal redemption price which, at the time the outstanding Warrants are called for redemption, is likely to be substantially less than the market value of your Warrants.

The value received upon exercise of the Warrants (1) may be less than the value the holders would have received if they had exercised their Warrants at a later time where the underlying share price is higher and (2) may not compensate the holders for the value of the Warrants.

In the event we elect to redeem the Warrants that are subject to redemption, we will mail the notice of redemption by first class mail, postage prepaid, not less than thirty days prior to the redemption date to the registered holders of the Warrants to be redeemed at their last addresses as they appear on the registration books. Any notice mailed in such manner will be conclusively presumed to have been duly given whether or not the registered holder received such notice, and we are not required to provide any notice to the beneficial owners of such warrants. Additionally, while we are required to provide such notice of redemption, we are not separately required to, and do not currently intend to, notify any holders of when the Warrants become eligible for redemption. If you do not exercise your Warrants in connection with a redemption, including because you are unaware that such Warrants are being redeemed, you would only receive the nominal redemption price for your Warrants.

Anti-takeover provisions contained in our amended and restated certificate of incorporation and bylaws, and in applicable law, could impair a takeover attempt.

Our amended and restated certificate of incorporation and bylaws afford certain rights and powers to our board of directors that could contribute to the delay or prevention of an acquisition that it deems undesirable, including:

- a classified board of directors with three-year staggered terms, which could delay the ability of stockholders to change the membership of a majority of our board of directors;

- the ability of our board of directors to issue shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquiror;

- the right of our board of directors to elect a director to fill a vacancy created by the expansion of our board of directors or the resignation, death or removal of a director, which may prevent stockholders from being able to fill vacancies on our board of directors;

- the requirement that a special meeting of stockholders may be called only by our board of directors or the chairman of the board of directors, which could delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and

- the requirement for the affirmative vote of holders of at least 75% of the voting power of all of the then-outstanding shares of the voting stock, voting together as a single class, to amend certain provisions of our amended and restated certificate of incorporation or to amend our amended and restated bylaws, which may inhibit the ability of an acquiror to effect such amendments to facilitate an unsolicited takeover attempt.

We are also subject to Section 203 of the Delaware General Corporation Law and other provisions of Delaware law that limit the ability of stockholders in certain situations to affect certain business combinations. Any of the foregoing provisions and terms that has the effect of delaying or deterring a change in control could limit the opportunity for stockholders to receive a premium for their shares of Common Stock, and could also affect the price that some investors are willing to pay for the Common Stock.

Our amended and restated certificate of incorporation provides, subject to limited exceptions, that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for certain stockholder litigation matters, which could limit stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, employees or stockholders.

Our amended and restated certificate of incorporation requires, to the fullest extent permitted by law, that derivative actions brought in our name, actions against directors, officers and employees for breach of fiduciary duty and other similar actions may be brought in the Court of Chancery in the State of Delaware or, if that court lacks subject matter jurisdiction, another federal or state court situated in the State of Delaware. These provisions will not apply to suits brought to enforce any liability or duty created by the Securities Act, the Securities Exchange Act, or any other claim for which the federal courts have exclusive jurisdiction. Any person or entity purchasing

or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and consented to the forum provisions in the amended and restated certificate of incorporation. In addition, the amended and restated certificate of incorporation and bylaws will provide that, to the fullest extent permitted by law, claims made under the Securities Act must be brought in federal district court.

This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, other employees or stockholders, which may discourage lawsuits with respect to such claims and result in increased costs for investors to bring a claim. Alternatively, if a court were to find the choice of forum provision contained in the amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, operating results and financial condition.

General Risk Factors

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, services, and trained personnel, as well as of our particular culture and the experience of our patients with our recommended sleep dentists. 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 or 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 headquarters, digital medical device modeling processes, and other manufacturing processes are principally located in regions that are subject to earthquakes and other natural disasters.

Our corporate headquarters, sales, and marketing organization and manufacturing processes are in a single facility located in Pleasanton, California. Such location is in an earthquake zone and may be subject to other natural disasters. If there is a major earthquake or any other natural disaster in a region where our facility is located, our ability to respond to customer inquiries or manufacture and ship our precisions intraoral medical devices could be compromised which could result in our customers experiencing a significant delay in receiving their devices and a decrease in service levels for a period of time. Any such business interruption could materially and adversely affect our business, financial condition, and results of operations.

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 our ProSomnus precision intraoral medical devices, and in turn indirectly on reimbursement from third-party payors for such devices. The amount that dentists receive in payment for our ProSomnus precision intraoral medical devices 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 payments 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 received by patients or dentists. 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 dentists 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 dentists' payor mix. Payor mix refers to the relative amounts we receive from the mix of persons or entities that pay or reimburse dentists for healthcare services. Payment or reimbursement amounts can vary from payor to payor, by geographic jurisdiction, and over time. 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 our ProSomnus precision intraoral medical devices, which in turn could have a material adverse effect on our business, prospects, results of operations, and financial condition.

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 and 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 acquisition and integration of another business or technology would divert management attention from other business activities, including our core business. 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 sleep medicine healthcare 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 depend on certain key personnel.

We substantially rely on the efforts of our current senior management, including our co-founder and Chief Executive Officer, Leonard Liptak and our co-founder and Chief Technology Officer, Sung Kim. 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 will have other business interests and obligations to other entities.

None of our independent directors 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, market our products internationally, 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, procedures, and controls across our business, as well as expand, train, motivate, and manage our workforce. 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.

Downturns or volatility in general economic conditions could have a material adverse effect on our business, financial condition, results of operations and liquidity.

Our revenues and profitability depend significantly on general economic conditions and the demand for our products in the markets in which our customers and their patients are located. Weaknesses in the global economy and financial markets, including the current weaknesses resulting from the ongoing COVID-19 pandemic or geopolitical instability, could lead to lower demand for our products. A decline in patient or customer demand can affect the need that customers have for our products, and the money or insurance available

to pay for our devices. Any further adverse changes in economic conditions, including any recession, economic slowdown or disruption of credit markets, or the outbreak of war or conflict, may also lead to lower demand for our products. Volatile and uncertain economic conditions can make it difficult to accurately forecast and plan future business activities.

All of these factors related to general economic conditions, which are beyond our control, could adversely impact our business, financial condition, results of operations and liquidity.

Our management team has limited experience managing a public company.

Most members of our management team have limited or no experience managing a publicly-traded company, interacting with public company investors, and complying with the increasingly complex laws, rules and regulations that govern public companies. There are significant obligations that we will be subject to relating to reporting, procedures and internal controls, and our management team may not successfully or efficiently manage our transition to being a public company. These new obligations and added scrutiny will require significant attention from our management and could divert their attention away from the day-to-day management of our business, which could adversely affect our business, operating results and financial condition.

Inadequate internal controls could result in inaccurate financial reporting.

If we fail to maintain an effective system of internal controls, we may not be able to accurately report our financial results. As a result, our stockholders could lose confidence in our financial reporting, which could adversely affect results of our business and our enterprise value.

We will need to undertake significant efforts to strengthen our processes and systems and adapt them to changes as our business evolves (including with respect to becoming a publicly traded company). This continuous process of maintaining and adapting our internal controls is expensive and time-consuming, and requires significant management attention. We cannot be certain that our internal control measures will, in the future, provide adequate control over our financial processes and reporting. Furthermore, as our business evolves and if we expand through acquisitions of other companies or make significant investments in other companies or enter into joint development and similar arrangements, our internal controls may become more complex and we will require significantly more resources to ensure our internal controls remain effective. Failure to implement required new or improved controls, or difficulties encountered in their implementation, could harm our operating results or cause us to fail to meet our reporting obligations. If we or our independent registered public accounting firm identify material weaknesses, the disclosure of that fact, even if quickly remediated, could reduce the market's confidence in our financial statements and harm our enterprise value.

Our actual operating results may differ significantly from our guidance.

From time to time, we provide forward looking estimates regarding our future performance that represent our management's estimates as of a point in time. These forward-looking statements are based on projections prepared by our management. These projections are not prepared with a view toward compliance with published guidelines of the American Institute of Certified Public Accountants, and neither our independent registered public accountants nor any other independent expert or outside party compiles or examines the projections and, accordingly, no such person expresses any opinion or any other form of assurance on our projections.

Projections are based upon a number of assumptions and estimates that, while presented with numerical specificity, are inherently subject to significant business, economic and competitive uncertainties and contingencies, many of which are beyond our control and are based upon specific assumptions with respect to future business decisions and conditions, some of which will change. The principal reason that we provide forward looking information is to provide a basis for our management to discuss our business outlook with stockholders. Forward-looking statements are necessarily speculative in nature, and it can be expected that some or all of the assumptions of our forward-looking statements will not materialize or will vary significantly from actual results. Accordingly, our forward-looking statements are only an estimate of what management believes is realizable as of the date of release. Actual results will vary from our forward-looking statements and the variations may be material. In light of the foregoing, investors are urged not to rely upon, or otherwise consider, our guidance in making investment decisions.

We qualify as an "emerging growth company" within the meaning of the Securities Act, and if we take advantage of certain exemptions from disclosure requirements available to emerging growth companies, it could make our securities less attractive to investors and may make it more difficult to compare our performance to the performance of other public companies.

We qualify as an "emerging growth company" as defined in Section 2(a)(19) of the Securities Act, as modified by the JOBS Act. As such, we are eligible for and intend to take advantage of certain exemptions from various reporting requirements applicable to other public companies that are not emerging growth companies for as long as we continue to be an emerging growth company, including (a) the exemption from the auditor attestation requirements with respect to internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act, (b) the exemptions from say-on-pay, say-on-frequency and say-on- golden parachute voting

requirements, and (c) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We will remain an emerging growth company until the earliest of (i) the last day of the fiscal year in which the market value of Common Stock that are held by non-affiliates exceeds $700.0 million as of June 30 of that fiscal year, (ii) the last day of the fiscal year in which we have total annual gross revenue of $1.235 billion or more during such fiscal year (as indexed for inflation), (iii) the date on which we have issued more than $1 billion in non-convertible debt in the prior three-year period or (iv) the last day of the fiscal year following the fifth anniversary of the date of the first sale of Common Stock in Lakeshore's initial public offering of units, consummated on June 15, 2021 (the "IPO"). In addition, Section 107 of the JOBS Act also provides that an emerging growth company can take advantage of the exemption from complying with new or revised accounting standards provided in Section 7(a)(2)(B) of the Securities Act as long as it is an emerging growth company. An emerging growth company can therefore delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected not to opt out of such extended transition period and, therefore, we may not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. Investors may find our securities less attractive because we will rely on these exemptions, which may result in a less active trading market for our securities.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our corporate headquarters are located at 5675 Gibraltar Drive, Pleasanton, CA 94588 and consists of approximately 32,200 square feet of space under a lease that expires on December 31, 2032. We also have a property at 5860 West Las Positas Blvd., Suite 25 Pleasanton, California, 94588, which consists of approximately 12,500 square feet of space under a lease that expires on January 31, 2024.

We believe that these facilities are adequate for our current and long-term operations.

Item 3. Legal Proceedings

To the knowledge of our management, there is no litigation currently pending or contemplated against us, any of our officers or directors in their capacity as such or against any of our property.

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 is traded on the Nasdaq Global Market under the symbol "OSA" and our warrants are traded on the Nasdaq Capital Market under the symbol "OSAAW."

Holders

On March 17, 2023, there were 328 holders of record of our common stock and 37 holders of record of our warrants.

Securities Authorized for Issuance Under Equity Compensation Plans.

As of December 31, 2022, there were 2,411,283 total shares reserved for issuance under the Company's 2022 Equity Incentive Plan.

Recent Sales of Unregistered Securities

On January 30, 2023, the Company issued 1,552 shares of Common Stock to a former shareholder of ProSomnus Holdings, Inc. valued at $10.00 per share, due to an administrative error in recording the number of shares held by such shareholder prior to the Business Combination. The shares were issued pursuant to and in accordance with the exemption from registration under the Securities Act, under Section 4(a)(2) and/or Regulation D promulgated under the Securities Act.

On February 9, 2023, the Company issued 49 shares of Common Stock to a former shareholder of ProSomnus Holdings, Inc. valued at $10.00 per share, due to an administrative error in recording the number of shares held by such shareholder prior to the Business Combination. The shares were issued pursuant to and in accordance with the exemption from registration under the Securities Act, under Section 4(a)(2) and/or Regulation D promulgated under the Securities Act.

On March 7, 2023, the Company canceled 3,883 shares of Common Stock to a former shareholder of ProSomnus Holdings, Inc. valued at $10.00 per share, due to an administrative error in recording the number of shares held by such shareholder prior to the Business Combination. The shares were issued pursuant to and in accordance with the exemption from registration under the Securities Act, under Section 4(a)(2) and/or Regulation D promulgated under the Securities Act.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Item 6. Selected Financial Data

We are a smaller reporting company as defined in Rule 12b-2 under the Exchange Act. As a result, pursuant to Item 301(c) of Regulation S-K, we are not required to provide the information required by this Item.

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

The following discussion and analysis of the financial condition and results of operations of ProSomnus Holdings, Inc. and its subsidiary prior to the Business Combination and for ProSomnus, Inc. and its subsidiaries subsequent to the Business Combination (for purposes of this section, collectively referred to as the "ProSomnus," "Company," "we," "us" and "our") should be read together with ProSomnus's audited consolidated financial statements as of and for the years ended December 31, 2022 and 2021, together with the related notes thereto, included in this report. This discussion contains forward-looking statements based upon current beliefs, plans, and expectations that involve numerous risks, uncertainties and assumptions, including, but not limited to, those described under the heading "Risk Factors." Actual results may differ materially from those contained in any forward-looking statements.

Overview

We are a commercial medical technology company focused on the development, manufacturing and marketing of precision intraoral medical devices, a new option for treating and managing patients with mild to moderate Obstructive Sleep Apnea ("OSA"). Each ProSomnus precision intraoral device is personalized based on the anatomy and treatment plan for each patient. Our patented precision devices are engineered to create unique, consistent and predictable biomechanical advantages that lead to effective, comfortable, economical and patient-preferred treatment outcomes for patients with OSA.

Our ProSomnus precision intraoral devices are classified by the U.S. Food and Drug Administration (the "FDA") as Class II medical devices for the treatment of snoring and mild to moderate OSA. We received pre-market notification and FDA clearance pursuant to Section 510(k) of the Federal Food, Drug, and Cosmetic Act ("FDCA") for our first intraoral device in July 2014 and our devices have been commercially available in the United States since August 2014. To date, over 200,000 ProSomnus precision devices have been prescribed for patients.

Sleep apnea is a serious and chronic respiratory disease that negatively impacts the sleep, health, and quality of life for millions of patients in the United States and around the world. OSA is the most common form of sleep apnea. OSA is a medical condition characterized by a cessation of breathing when the tongue, soft palate, and other related tissues in the back of the throat collapse and block the upper airway during sleep, temporarily decreasing the oxygen concentration in the blood. During an OSA episode, the diaphragm and chest muscles must work harder to overcome the obstruction and open the airway. These episodes disrupt the sleep cycle, reduce airflow to vital organs, stress the body, and create a negative feedback loop. If untreated, OSA increases the risk of high blood pressure, hypertension, heart failure, stroke, coronary artery disease and other life-threatening diseases. OSA is associated with a reduction in quality-of-life factors including a higher risk of motor vehicle and operator accidents, workplace errors, absenteeism and more.

Until ProSomnus, there have been few alternatives for OSA patients who refuse or fail CPAP. Historically, treatment alternatives to CPAP have consisted of surgical procedures or legacy oral appliances. Surgical procedures, such as hypoglossal nerve stimulation and maxillomandibular advancement, can be invasive, irreversible, expensive, and only suitable for a narrow range of patient types.

Legacy oral appliances, historically, have been associated with inconsistent and unreliable performance. We believe that there is both an urgent clinical need and a strong market opportunity for a treatment alternative that is effective, non-surgical, convenient, and more economical.

We market and sell our precision intraoral devices to providers in the United States and in select countries around the world through a direct sales force. Our direct sales force focuses their education, promotional and sales efforts on dentists who have developed a specialty in dental sleep medicine, and the physicians who are actively treating OSA. We intend to make investments to scale our commercial reach in identified markets around the world.

We generated revenue of $19.4 million, with a gross margin of 52.9% and a net loss of $7.1 million, for the year ended December 31, 2022, compared to revenue of $14.1 million, with a gross margin of 51.9% and a net loss of $6.0 million, for the year ended December 31, 2021.

Description of Certain Components of Financial Data

Revenue, net

We derive all of our revenue from the sale of our custom precision intraoral medical devices used to treat patients diagnosed with Obstructive Sleep Apnea. Our revenue recognition policies are discussed in more detail in Note 1 to our consolidated financial statements and notes thereto included elsewhere in this report.

Cost of Revenue

Cost of revenue consists primarily of materials and the costs related to the production of the intraoral device, including employee compensation, stock-based compensation, other employee-related expenses, inbound shipping and allocable manufacturing overhead costs. ProSomnus has a policy to classify initial recruiting and training costs of new manufacturing employees as part of research and development expenses in the consolidated statements of operations.

Research and development

Research and development expenses consist of production costs for prototypes, test and pre-production units, supplies, consulting, clinical studies and personnel costs, including salaries, bonuses and benefits. Most of our research and development expenses are related to developing new products and services. Consulting expenses are related to research and development activities as well as clinical and regulatory activities and certain third-party engineering costs. Research and development expenses are expensed as incurred. We expect to continue to make investments in product development. As a result, research and development expenses are expected to increase modestly in absolute dollars as the research and development efforts increase.

Sales and marketing

Sales and marketing expenses consist of salaries, commissions, bonuses, benefits and travel costs for employees engaged in sales and marketing activities, as well as website, advertising, conferences and other promotions. By design, sales and marketing costs are tied to sales performance and increase as sales and corresponding revenues increase.

General and administrative

General and administrative expenses primarily consist of labor, bonuses, benefits, general insurance, office expenses and outside services. Outside services consist of audit, tax, legal and other professional fees. We expect that general and administrative expenses will increase in absolute dollars as a result of operating as a public company.

Other income (expense), net

Other income (expense) primarily relates to interest expense as well as a gain from change in fair value of warrants and convertible debt (including interest on Senior and Subordinated convertible notes), a changes in fair value of Earn-out liability, loss on the extinguishment of debt related to the Second Amendment and the Convertible Bridge Loan Advance and gain from forgiveness of Paycheck Protection Program (“PPP”) loans,

The components of interest expense include interest expense payable under subordinated notes, subordinated loan and security agreements, unsecured subordinated promissory notes, equipment financing and capital lease obligations.

Provision for income taxes

The Company accounts for income taxes under an asset and liability approach. Deferred income taxes reflect the impact of temporary differences between assets and liabilities recognized for financial reporting purposes and such amounts recognized for income tax reporting purposes as well as net operating loss carryforwards and tax credit carryforwards. The Company records a valuation allowance to reduce deferred tax assets to the amount that is believed "more-likely-than-not" to be realized. Realization of deferred tax assets is dependent upon future pretax earnings, the reversal of temporary differences between book and tax income, and the expected tax rates in future periods. The Company recorded a full valuation allowance as of December 31, 2022 and December 31, 2021. Based on available evidence, we believe that it is more likely than not that we will be unable to utilize all our deferred tax assets in the future.

The Company evaluates the tax positions taken in the course of preparing its tax returns to determine whether tax positions are more-likely-than-not of being sustained by the applicable tax authority. Tax benefits of positions not deemed to meet the more-likely-than-not threshold would be recorded as a tax expense in the current year. The amount recognized is subject to estimate and management judgment with respect to the likely outcome of each uncertain tax position. The amount that is ultimately sustained for an individual uncertain tax position or for all uncertain tax positions in the aggregate could differ from the amount that is initially recognized. Interest and penalties associated with unrecognized tax benefits, if any, are classified as income tax expense in the statement of operations.

COVID-19

In March 2020, the World Health Organization declared the global outbreak of COVID-19 to be a pandemic. We continue to closely monitor the recent developments surrounding the continued spread and potential resurgence of COVID-19. The COVID-19 pandemic has had, and is expected to continue to have, an adverse impact on our operations, particularly as a result of preventive and precautionary measures that we, other businesses, and governments are taking. Demand may shift over time, as the impacts of the COVID-19 pandemic may go through several phases of varying severity and duration.

Please refer to the section titled "Risk Factors" included elsewhere in this report for more information.

Results of Operations

The following is a discussion of our results of operations for the periods shown below, and our accounting policies are described in Note 1 in our consolidated financial statements for the years ended December 31, 2022 and 2021 included elsewhere in this annual report.

	Year Ended December 31,		Change		Year Ended December 31,		Change	
	2022	2021	$	%	2021	2020	$	%
Revenue, net	$ 19,393,343	$ 14,074,649	$ 5,318,694	37.8 %	$ 14,074,649	$ 8,286,050	$ 5,788,599	69.9 %
Cost of Revenue	9,127,338	6,764,319	2,363,019	34.9 %	6,764,319	4,165,659	2,598,660	62.4 %
Gross profit	10,266,005	7,310,330	2,955,675	40.4 %	7,310,330	4,120,391	3,189,939	77.4 %
Gross margin %	*52.9 %*	*51.9 %*			*51.9 %*	*49.7 %*		
Operating expenses								
Research and development	2,981,271	1,889,208	1,092,063	57.8 %	1,889,208	1,470,748	418,460	28.5 %
Sales and marketing	8,865,328	5,776,084	3,089,244	53.5 %	5,776,084	3,515,976	2,260,108	64.3 %
General and administrative	9,894,899	4,467,576	5,427,323	121.5 %	4,467,576	3,309,319	1,158,257	35.0 %
Total operating expenses	21,741,498	12,132,868	9,608,630	79.2 %	12,132,868	8,296,043	3,836,825	46.2 %
Other (expense) income								
Interest expense	(6,119,806)	(3,245,220)	(2,874,586)	88.6 %	(3,245,220)	(2,007,363)	(1,237,857)	61.7 %
Forgiveness of PPP loans	—	2,281,262	(2,281,262)	n/m	2,281,262	—	2,281,262	n/m
Change in fair value of earnout liability	9,260,000	—	9,260,000	n/m	—	—	—	n/m
Change in fair value of debt	553,235	—	553,235	n/m	—	—	—	n/m
Change in fair value of warrant liability	3,234,586	(190,911)	3,425,497	n/m	(190,911)	—	(190,911)	n/m
Loss on extinguishment of debt	(2,597,842)	—	(2,597,842)	n/m	—	10,000	(10,000)	n/m
Total other (expense) income	4,330,173	(1,154,869)	5,485,042	(474.9)%	(1,154,869)	(1,997,363)	842,494	(42.2)%
Net loss before income taxes	(7,145,320)	(5,969,755)	(1,175,565)	19.7 %	(5,969,755)	(6,155,350)	185,595	(3.0)%
Provision for income taxes	—	—	—	— %	—	—	—	— %
Net loss	$ (7,145,320)	$ (5,977,407)	$ (1,175,565)	19.7 %	$ (5,969,755)	$ (6,155,350)	$ 185,595	(3.0)%

(n/m = not meaningful)

Comparison of the Fiscal Years ended December 31, 2022 and 2021

Revenues increased by $5.3 million, or 37.8%, for the year ended ended December 31, 2022, compared to $14.1 million for the year ended ended December 31, 2021. This increase was primarily driven by increased adoption of the use of our precision devices, increased sales and marketing investments, and mix shift to the new EVO Product, all of which contributed to increased unit volumes.

Revenue from the Company's largest customer was 5.7% for the year ended December 31, 2022, and 6.0% for the year ended December 31, 2021.

Total cost of revenue increased by $2.4 million, or 34.9 %, for the year ended December 31, 2022, compared to $6.8 million for the year ended December 31, 2021. The increase was primarily due to product costs associated with higher sales volume of our devices and an increase in the cost of materials and supplies.

Gross profit increased by $3.0 million, or 40.4% for the year ended December 31, 2022, compared to $7.3 million for the year ended December 31, 2021. The increase was attributable to an increase in Net Revenue of $5.3 million as discussed above, partially offset by an increase in Cost of Revenue of $2.3 million.

Research and development expenses increased by $1.1 million, or 57.8%, for the year ended December 31, 2022, compared to the year ended December 31, 2021. This increase was primarily driven by an increase in headcount-related personnel and consulting costs of $0.9 million and $0.2 million in other expenses in research and development.

Sales and marketing expenses increased by $3.1 million, or 53.5%, for the year ended December 31, 2022, compared to the year ended December 31, 2021. This increase was primarily driven by an increase in personnel and consulting-related expenses of $1.7 million due to expansion of the sales team. Sales and marketing events increased $1.0 million, and travel and in-person events increased $0.4 million.

General and administrative expenses increased by $5.4 million, or 121.5%, for the year ended December 31, 2022, compared to the year ended December 31, 2021. This increase was driven primarily by $2.2 million on account of stock based compensation, $1.5 million related to increase in personnel costs and bonuses, $1.1 million increase in costs that scale with revenue including credit card fees, recruiting, software, utilities, and depreciation and $0.3 million increase in costs related to investor relations and $0.1 million related to compensation plan tools.

Total other expense decreased by $5.5 million, or 474.9%, from an expense of $1.1 million for the year ended December 31, 2021, to an income of $4.3 million for year ended December 31, 2022. This decrease was primarily driven by change in fair value of earnout liabilities, debt and warrant liabilities of $9.3 million,$ 0.6 million and $3.4 million, respectively. This was offset by an increase of $2.9 million in interest expenses and a $2.5 million loss of extinguishment of debt. There was a gain of $2.3 million from Payroll Protection Program loan forgiven in year ended December 31, 2021.

Factors Affecting Results of Operations

The following factors have been important to our business, and we expect them to impact our results of operations and financial condition in future periods:

(a) Expansion of North American direct sales organization and international expansion

The core focus of our sales initiative is to expand our direct sales organization in North America. With representatives located in high-value metropolitan areas, the direct sales organization will focus primarily on dentists and physicians who are practicing sleep medicine. The main purpose of this initiative is to increase case volume from these dentists and physicians by facilitating a referral relationship between dentists and physicians, helping them expand the dental sleep medicine aspect of their practices and educating them on the advantages of the ProSomnus intraoral devices. We also intend to further expand our sales to integrated health systems and hospital networks. We are currently initiating the marketing and sales of our ProSomnus intraoral devices in several European countries and intend to further expand our marketing and direct sales into international markets.

(b) Product line extensions and remote patient monitoring services

We intend for product line extensions to focus on enabling ProSomnus to capture a larger share of treatments for patients with OSA, snoring and other related sleep-disordered breathing conditions. We expect that each product line extension will be designed to optimize ProSomnus products for a wider range of case types, treatment philosophies, and indications. We expect that each product line extension will utilize our unique manufacturing platform and potentially create additional opportunities for intellectual property.

We received FDA clearance for an intraoral device that enables remote patient monitoring services in November 2020. The sales of such remote patient monitoring services in connection with our intraoral devices could result in an additional recurring revenue stream that is reimbursable by insurance. Our remote patient monitoring services will be based on the incorporation of a sensor into the ProSomnus intraoral devices that provides continuous monitoring of physiological health data that physicians want and cannot typically obtain from CPAP or other intraoral appliance therapy devices. Our market research indicates that our remote patient monitoring services could be a significant driver of greater market acceptance and expansion and result in significant future revenues.

LIQUIDITY AND CAPITAL RESOURCES

Going Concern and Management's Plans

On December 6, 2022, on consummation of the Busines Combination, we received $4.92 million of cash held in Lakeshore's trust account from its initial public offering, net of redemptions of Lakeshore's public stockholders of $24.4 million; $10.25 million of cash in connection with the PIPE Equity financing and approximately $30 million in proceeds from the Convertible Notes offering. These proceeds were used to pay transaction expenses and other liabilities of Lakeshore, pay certain transaction expenses of ProSomnus, and pay off approximately $11.53 million in debt of ProSomnus at closing, with the remaining being deposited in ProSomnus' cash account.

We have incurred significant cash burn and recurring net losses, which include a net loss of $7.1 million and $6.0 million for the fiscal years ended December 31, 2022 and 2021, respectively, and have incurred an accumulated deficit of $210.8 million as of December 31, 2022.

As we continue to invest in the development of new products and sales and marketing, we expect to continue to incur cash burn and recurring net losses for the foreseeable future until such time that our product and services sales generate enough gross profit to cover our operating expenses. Based on cash flow projections from operating and financing activities and existing balance of cash and cash equivalents and investments, management is of the opinion that the Company has sufficient funds for sustainable operations, and it will be able to meet its payment obligations from operations and debt related commitments for at least one year from the issuance date of these financial statements. Based on the above considerations, the Company's financial statements have been prepared on a going concern basis, which contemplates the realization of assets and liquidation of liabilities during the normal course of operations.

The Company's ability to continue as a going concern is dependent on management's ability to control operating costs and maintain revenue growth forecast. Management believes the Company will be able to meet its obligations and operations for twelve months after the issuance of the consolidated financial statements in March 2023. However, additional funding will be necessary to fund future discovery research, pre-clinical and clinical activities. We intend to seek additional funding through public financings, debt financings, collaboration agreements, strategic alliances and licensing arrangements. Although we have been successful in raising capital in the past, there is no assurance that we will be successful in obtaining such additional financing on acceptable terms, or at all, and we may not be able to enter into collaborations or other arrangements. If we are unable to obtain funding, we could be forced to delay, reduce or eliminate our research and development programs, product portfolio expansion or commercialization efforts, which could adversely affect our business prospects, even our ability to continue operations

(a) Cash and Cash equivalents

As of December 31, 2022, we had cash and cash equivalents of $15.9 million. Our future capital requirements may vary from those currently planned and will depend on various factors including further development costs, commercialization strategy, international expansion, and regulatory costs. If we need additional funds and are unable to obtain funding on a timely basis, we may need to significantly curtail our product development and commercialization efforts to provide sufficient funds to continue our operations, which could adversely affect our business prospects.

(b) Cash flows

The following table summarizes our cash flows for the periods indicated:

	Year Ended December 31,	
	2022	2021
Net cash provided by (used in):		
Operating activities	$ (10,238,905)	$ (4,634,934)
Investing activities	(1,353,662)	(301,302)
Financing activities	26,008,126	4,881,264
Net increase (decrease) in cash and cash equivalents	$ 14,415,559	$ (54,972)

Net cash used in operating activities

For the year ended December 31, 2022, net cash used in operating activities of $10.2 million was due primarily to a net loss of $7.1 million, changes in operating assets and liabilities of $1.5 million, offset by non-cash items of $1.6 million. Changes in operating assets and liabilities were driven primarily by $1.7 million of prepaid expenses, and other current assets of $1.1 million and an increase in other assets of $0.1 million, offset by an increase in accounts payable of $1.1 million, and an increase in accrued compensation and other accrued expenses of $0.4 million. Non-cash items primarily consisted of depreciation, amortization, non-cash interest expense, change in fair value of earnout liabilities of $9.3 million, change in fair value of debt of $0.6 million, change in fair value of warrant liabilities of $3.2 million and loss on extinguishment of debt of $2.6 million.

For the year ended December 31, 2021, net cash used in operating activities of $4.6 million was due primarily to a net loss of $6.0 million, non-cash items of $0.3 million and changes in operating assets and liabilities of $1.6 million. Non-cash items primarily consisted of forgiveness of the PPP loans, depreciation, and non-cash interest expense. Changes in operating assets and liabilities were driven primarily by an increase in accrued expenses and accounts payable of $2.6 million, partially offset by an increase in accounts receivable and inventory of $0.9 million.

Net cash used in investing activities

For the year ended December 31, 2022, net cash used in investing activities of $1.4 million was due primarily to purchases of property and equipment.

For the year ended December 31, 2021, net cash used in investing activities of $0.3 million was due primarily to purchases of property and equipment.

Net cash provided by financing activities

For the year ended December 31, 2022, net cash provided by financing activities of $26.0 million was primarily due to proceeds of $9.5 million from PIPE equity financing, $4.9 million from Lakeshore trust, $27.5 million from issuance of Senior and Subordinated Convertible notes, $24.4 million from line of credit, $5.3 million from unsecured subordinated promissory notes and $0.4 million from proceeds of subordinated notes. Financing cash inflows were partially offset by repayments of $24.9 million on the line of credit, repayment of unsecured subordinated promissory notes of $0.6 million, principal payments under finance lease and equipment financing obligations of $1.3 million, repayments of subordinated loan and security agreements of $10.7 million, and repayments of subordinated notes of $0.1 million and payment of issuance costs on account of merger transaction of $8.2 million.

For the year ended December 31, 2021, net cash provided by financing activities of $4.9 million was primarily due to proceeds of $17.5 million from borrowings under the line of credit, proceeds of $2.8 million from issuance of subordinated notes, proceeds of $2.0 million from the issuance of a subordinated loan and security agreement, and $1.0 million in proceeds from the issuance of notes payable under the PPP loan program. Total financing cash inflows amounted to $23.3 million and were partially offset by repayments of $17.0 million on the line of credit, principal payments under capital lease obligations of $0.8 million, and repayments of subordinated loan and security agreements of $0.6 million.

(c) Contractual obligations

Below is a summary of short-term and long-term anticipated cash requirements under contractual obligations existing as of December 31, 2022.

	Total	2023	After 2023
Recorded contractual obligations:			
Senior Convertible notes	$ 13,651,000	$ —	$ 13,651,000
Subordinated Convertible note	10,355,681	—	10,355,681
Other*	9,075,220	1,282,603	7,792,617
Total	$ 33,081,901	$ 1,282,603	$ 31,799,298

** Represents finance and operating lease liabilities, equipment financing obligations and payable under commission settlement*

During September 2022, we entered into an agreement with an effective date of January 1, 2022, with the chairman of our Board of Directors to provide consulting services. The consultant received $120,000 in the year ended December 31, 2022. Upon completion of the business combination, the consultant became our full-time employee as of January 1, 2023.

During January 2022, we entered into an agreement with an external consulting firm to provide investor and public relations consulting services. The monthly fee was $20,000 prior to business combination. Additionally, upon completion of the business combination, the vendor received a payment of $200,000 and may receive an additional $200,000 in the form of common stock. We pay a fee of $34,000 per month after the business combination. The agreement terminates on the last date of the month following the second anniversary of the business combination completion date.

During November 2021, we entered into an agreement with an external consulting firm to act as the placement agent for a future business combination. Upon completion of the business combination transaction, the consulting firm earned approximately nine percent of the gross proceeds raised in the transaction, these were paid in common stock of the company.

During March 2021, we entered into an agreement with an external consulting firm to provide consulting and advisory services. Upon completion of the business combination transaction, the consulting firm was paid compensation of approximately $1.2 million, which was paid in common stock of the company.

As of December 31, 2022, we did not have any off-balance sheet arrangements that have, or are reasonably likely to have, a current or future material effect on our consolidated financial condition, results of operations, liquidity, capital expenditures or capital resources.

Critical Accounting Policies and Significant Judgments and Estimates

Our consolidated financial statements are prepared in accordance with U.S. GAAP. The preparation of our consolidated financial statements in conformity with U.S. GAAP requires us to make estimates and assumptions that affect certain reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. While our significant accounting policies are described in more detail in Note 1 in our consolidated financial statements for the years ended December 31, 2022 and 2021 included elsewhere in this report, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

(a) Emerging Growth Company

ProSomnus 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 independent registered public accounting firm attestation requirements of Section 404 of the Sarbanes- Oxley Act, reduced disclosure obligations regarding executive compensation in its periodic reports and proxy statements, 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 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. ProSomnus has elected not to opt out of such extended transition period which means that when a standard is issued or revised and it has different application dates for public or private companies, ProSomnus, as an emerging growth company, can adopt the new or revised standard at the time private companies adopt the new or revised standard. This may make comparison of ProSomnus's financial statements with another public company which is neither an emerging growth company nor an emerging growth company which has opted out of using the extended transition period difficult or impossible because of the potential differences in accounting standards used.

(b) Inventory

Inventory is recorded at the lower of cost or net realizable value under standard costing method of accounting. Inventories primarily consist of purchased raw materials. We regularly review whether the net realizable value of inventory is lower than its carrying value. If the valuation shows that the net realizable value is lower than the carrying value, we take a charge to cost of revenue and directly reduce the carrying value of the inventory. Indicators that could result in inventory write-downs include damaged or slow-moving materials and supplies.

(c) Property and Equipment

Property and equipment are stated at cost, less accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful lives of the related assets. Estimated useful lives are as follows:

Manufacturing equipment	3 to 7 years
Computers and software	3 years
Furniture	7 years
Leasehold Improvements.	Shorter of remaining lease term or estimated useful life

Maintenance and repairs are charged to operations as incurred.

Through December 31, 2022, equipment capitalized under capital lease obligations was included in property and equipment. Property and equipment capitalized under capital lease obligations were amortized using a straight-line method over the shorter of the life of the lease or the useful life of the asset, which ranges from 3 to 7 years, and was included in depreciation expense in the consolidated statements of operations. On January 1, 2022 the Company adopted Accounting Standards Update ("ASU") 2016-02, Leases ("ASC 842"), which impacted the classification of equipment formerly capitalized under capital lease obligations. The equipment related to capital leases, now finance leases, have been reclassified from property and equipment to right-of-use assets on the consolidated balance sheet.

(d) Redeemable Convertible Preferred Stock

We record all shares of redeemable convertible preferred stock at their respective issuance price, less issuance costs on the dates of issuance. The redeemable convertible preferred stock was presented outside of stockholders' deficit in the consolidated balance sheets.

(e) Convertible Notes

The Company accounts for its derivatives in accordance with ASC 815-10, Derivatives and Hedging, or ASC 815-15, Embedded Derivatives, depending on the nature of the derivative instrument. ASC 815 requires each contract that is not a derivative in its entirety be assessed to determine whether it contains embedded derivatives that are required to be bifurcated and accounted for as a derivative financial instrument. The embedded derivative is bifurcated from the host contract and accounted for as a freestanding derivative if the combined instrument is not accounted for in its entirety at fair value with changes in fair value recorded in earnings, the terms of the embedded derivative are not clearly and closely related to the economic characteristics of the host contract, and a separate instrument with the same terms as the embedded derivative would qualify as a derivative instrument. Embedded derivatives are measured at fair value and remeasured at each subsequent reporting period, and recorded within convertible notes, net on the accompanying Consolidated Balance Sheets and changes in fair value recorded in other expense within the Consolidated Statements of Operations.

The Company determined the Senior and Subordinated convertible notes, issued in connected with the merger transaction, contained multiple embedded derivatives that are required to be bifurcated, two of which are conversion features. As per ASC 815, if there is a conversion feature that is required to be bifurcated, the cash conversion feature and beneficial conversion feature guidance is not applicable to such conversion feature and the fair value election is allowable provided the debt was not issued at a substantial premium. As the proceeds received at issuance from these Convertible Notes do not exceed the principal amount that will be paid at maturing, there is no substantial premium.

Under the fair value election as prescribed by ASC 815, the Company will not bifurcate the embedded instruments and fair value the Senior and Subordinated convertible notes. The company will record changes in fair value through the consolidated statement of operations as a fair value adjustment of the convertible debt each reporting period, with the portion of the change that results from a change in the instrument-specific credit risk recorded separately in other comprehensive income, if applicable. The Company has also elected not to separately present interest expense related to the Senior and Subordinated Promissory Notes and the entire change in fair value of the instrument will be recorded as a fair value adjustment of convertible debt within the consolidated statement of operations.

(f) Warrants

We account for warrants as either equity-classified or liability-classified instruments based on an assessment of the warrant's specific terms and applicable authoritative guidance in Financial Accounting Standards Board ("**FASB**") Accounting Standards Codification ("**ASC**") 480, Distinguishing Liabilities from Equity ("**ASC 480**") and ASC 815, Derivatives and Hedging ("**ASC 815**"). The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, meet the definition of a

liability pursuant to ASC 480, and whether the warrants meet all of the requirements for equity classification under ASC 815, including whether the warrants are indexed to our own common stock, among other conditions for equity classification. This assessment, which requires the use of professional judgment, is conducted at the time of warrant issuance and as of each subsequent reporting period end date while the warrants are outstanding.

For issued or modified warrants that meet all of the criteria for equity classification, the warrants are recorded as a component of additional paid-in capital at the time of issuance. For issued or modified warrants that do not meet all the criteria for equity classification, the warrants are recorded at their initial fair value on the date of issuance, and each balance sheet date thereafter. Changes in the estimated fair value of the warrants are recognized as a non-cash other income or expense on the consolidated statements of operations.

(g) Revenue Recognition

The Company creates customized precision milled intraoral devices. When devices are sold, they include an assurance-type warranty guaranteeing the manufacture of the product in accordance with the prescription for a period of 3 years from the date of sale.

In accordance with ASU 2014-09, "Revenue from Contracts with Customers (Topic 606)," the Company recognizes revenue upon meeting the following criteria:

- Identifying the contract with a customer: Customers submit authorized prescriptions and dental impressions to the Company. Authorized prescriptions constitute the contract with customers.

- Identifying the performance obligations within the contract: The sole performance obligation is the shipment of a completed customized intraoral device.

- Determining the transaction price: Prices are determined by standardized pricing sheets and adjusted for estimated returns, discounts and allowances.

- Allocating the transaction price to the performance obligations: The full transaction price is allocated to the shipment of the completed intraoral device as it is the only element in the transaction.

- Recognize revenue as the performance obligation is satisfied: revenue is recognized upon transfer of control which occurs upon shipment of the product.

The Company does not require collateral or any other form of security from customers. Inbound shipping and handling costs related to sales are billed to customers. Outbound shipping costs are not billed to customers and are included in sales and marketing expenses. Taxes collected from customers and remitted to governmental authorities are excluded from revenue.

Standalone selling price for the various intraoral device models are determined using the Company's standard pricing sheet. The Company invoices customers upon shipment of the product and invoices are due within 30 days. Amounts that have been invoiced are recorded in accounts receivable and revenue as all revenue recognition criteria have been met. The Company does not offer a financing component related to its sales arrangements.

We utilize the practical expedient which permits expensing of costs to obtain a contract when the expected amortization period is one year or less, which typically results in expensing commissions paid to employees. We expense sales commissions paid to employees as revenue are recognized.

ProSomnus devices are custom manufactuctures to match the patients specific anatomy and the prescription submitted by the healthcare provider for each patient. A prescription includes four components: (1) records of the patient's upper dental anatomy; (2) records for the patient's lower dental anatomy; (3) records for the patient's jaw position; and (4) documentation that includes required information such as the healthcare provider's license number and any additional instructions. The records of the patient's upper dental anatomy are used to personalize the upper splint component for the ProSomnus device to ensure that the upper splint component fits the patient's upper teeth. The records of the patient's lower dental anatomy are used to personalize the lower splint component for the ProSomnus device to ensure that the lower splint component fits the patient's lower teeth. The records of the patient's jaw position are used to personalize the relationship of the ProSomnus device's prescription posts which determine the positional relationship between the upper and lower splint components for the ProSomnus device. The aforementioned description of personalization is included in our regulatory documents such as our FDA 510(k) clearances. After the typical sale we are not required to perform any additional personalization.

Key contract terms for intraoral devices include:

- a 3-year warranty from the date of manufacture for all devices, except for Medicare devices, which have a 5-year warranty. Our warranty covers the device against defects in workmanship and materials. ProSomnus will replace or repair any device with unsatisfactory workmanship or materials quality;

- no warranty for device fit if the provided patient records are distorted. ProSomnus will not offer a warranty if the records do not meet basic requirements, such as minimum vertical clearance;

- the warranty is voided if device damage is attributed to patient misuse or if the healthcare provider makes structural changes to the device;

- the healthcare provider must return a defective device, as part of our compliance with our quality management system; and

- our standard turnaround time for manufacturing a device is seven business days plus shipping time.

Our only post delivery performance obligation associated with the sale of our device is our warranty. There are no obligations to train sleep dentists, sleep physicians or other providers.

Our transaction prices are our list prices for our products less the applicable discount schedule

- *List prices*. Our list prices consider competitive reference prices, economic value added relative to competitive products, manufacturing costs, manufacturing capacity dynamics, insurance reimbursement amounts, and our business strategy. We continuously monitor these considerations for the purposes of establishing list prices for new products and for managing the list prices for existing products. We evaluate existing list prices at least annually. However, we also evaluate existing list prices whenever there is a major change in any of these components (for example, a competitor increases their list prices 20%).

- Competitive Reference Prices. We continuously monitor competitive reference prices and weigh the pros and cons of adjusting our list prices when competitors price new products or adjust list prices for existing products.

- Manufacturing Costs. We continuously monitor manufacturing costs. There are, generally, five types of manufacturing costs that we consider when evaluating the list price of a product: direct labor, materials, supplies, factory overhead costs and factory overhead labor. We continuously monitor these five types of manufacturing costs and evaluate our list prices accordingly.

- Insurance Reimbursement Amounts. Payors routinely change the coverage policies and amounts for various products and procedures. We continuously monitor these reimbursement trends and the implications these trends might have on the price sensitivity of our customers.

- Business Strategy. There are certain situations where the company may wish to adjust a list price upward or downward based on business strategy. For example, if the company is launching a new product, the company may wish to adjust list prices downward to stimulate trial orders for the new product.

- *Discount Schedules*. The Company offers discount schedules that are applied to the relevant list price for a product. The discount schedule is based on certain order volume thresholds. The greater the order volume, the higher the discount. The rationale for volume-based discounts is that it is more efficient for our Company to service customers with higher order volumes. Thus, our Company shares these efficiencies with customers in the form of the volume-based discounts with the objective of lower costs to treat patients.

As a result of our list prices and discount schedule being somewhat formulaic, our pricing is consistent for customers who fall within the same order volume level.

(h) Earn-out Arrangement

In connection with the Business Combination and pursuant to the Merger Agreement, eligible legacy ProSomnus stockholders and stock options and restricted share units (RSUs) holders are entitled to receive an aggregate of 3,000,000 shares of the Company's Class A common shares ("Earn-out Shares") upon the Company achieving certain Earn-out triggering events during the Earn-out Period (as described in Note 10 of our consolidated financial statements included in this Annual Report Form 10-K).

In accordance with ASC 815, Earn-out Shares issuable these common stockholders in respect of such common stock are not solely indexed to the common stock and therefore are accounted for as Earn-out liability on the consolidated balance sheet at the date of merger transaction and subsequently remeasured at each reporting date with changes in fair value recorded a component of other expense, net in the consolidated statements of operations.

The estimated fair value of the Earn-out Shares is determined using a Monte Carlo simulation prioritizing the most reliable information available. The assumptions utilized in the calculation are based on the achievement of certain stock price milestones, including the current Company common stock price, expected volatility, risk-free rate, expected term and dividend rate. If the applicable triggering event is achieved for a tranche, the Company will account for the Earn-out Shares for such tranche as issued and outstanding common stock. The Earn-out triggering events were not achieved as of December 31, 2022.

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 1 to our consolidated financial statements and notes thereto for the years ended December 31, 2022 and 2021 included elsewhere in this report.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to market risk in the ordinary course of business. Market risk represents the risk of loss that may impact our results of operations or financial position due to adverse changes in financial market prices and rates. Our market risk exposure is primarily a result of fluctuations in interest rates. We do not hold, issue, or enter into any financial instruments for speculative or trading purposes.

Interest rate risk

Our cash and cash equivalents as of December 31, 2022 consisted of $15.9 million in bank accounts. We believe that we do not have any material exposure to changes in the fair value of these assets. We do not believe that a hypothetical 10% change in interest rates would have a material effect on our consolidated cash flows or operating results.

Effects of Inflation

Inflation generally affects us by increasing our cost of raw materials, labor and research and development expenses. We do not believe inflation has had a material effect on our results of operations during the periods presented in this report.

Item 8. Financial Statements and Supplementary Data

PROSOMNUS, INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors of Prosomnus, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of Prosomnus, Inc. (the "Company") as of December 31, 2022 and the related consolidated statement of operations, redeemable convertible preferred stock and stockholders' deficit and cash flows for the ended December 31, 2022 and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022, and the results of its operations and its cash flows for the year ended December 31, 2022 in conformity with accounting principles generally accepted in the United States of America.

Change in Accounting Principle

As discussed in Notes 2, 4 and 7 to the consolidated financial statements, the Company has changed its method of accounting for leases as January 1, 2022 due to the adoption of Accounting Standards Update 2016-02, Leases (Topic 842).

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audit. 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 audit 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 audit 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 audit 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 audit 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 audit provides a reasonable basis for our opinion.

/s/ Marcum LLP

Marcum LLP

We have served as the Company's auditor since 2022

Portland, Maine
April 14, 2023

PCAOB ID Number 688

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of ProSomnus, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of ProSomnus, Inc. and its subsidiary (collectively, the "Company") as of December 31, 2021, the related consolidated statements of operations, redeemable convertible preferred stock and stockholders' deficit and cash flows for the year then ended, and the related notes to the consolidated financial statements (collectively, the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2021, and the results of its operations and its cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audit. 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 U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB and with auditing standards generally accepted in the United States of America (GAAS). 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 audit, 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 audit 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 audit 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 audit provides a reasonable basis for our opinion.

Emphasis of Matter

As discussed in Note 1 to the financial statements, the Company relies on its principal stockholder's support for its financing needs.

/s/ Singer Lewak LLP

We have served as the Company's auditor from 2014 to 2022

San Jose, California
April 2, 2022

PROSOMNUS, INC.

CONSOLIDATED BALANCE SHEETS
As of December 31, 2022 and 2021

	December 31, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 15,916,141	$ 1,500,582
Accounts receivable, net of allowance for doubtful accounts of $162,635 and $100,000 as of December 31, 2022 and 2021, respectively	2,843,148	2,098,982
Inventory	639,945	378,769
Prepaid expenses and other current assets	1,846,870	148,207
Total current assets	21,246,104	4,126,540
Property and equipment, net	2,404,402	3,356,595
Right-of-use assets, net	9,283,222	—
Other assets	262,913	154,797
Total assets	$ 33,196,641	$ 7,637,932
LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 2,101,572	$ 955,648
Accrued expenses	3,706,094	3,078,578
Revolving line of credit	—	587,816
Subordinated loan and security agreement	—	968,493
Equipment financing obligation	58,973	55,333
Finance lease liabilities	1,008,587	926,104
Operating lease liabilities	215,043	—
Total current liabilities	7,090,269	6,571,972
Subordinated loan and security agreement, net of current portion	—	6,589,563
Equipment financing obligation, net of current portion	185,645	244,617
Finance lease liabilities, net of current portion	2,081,410	866,853
Operating lease liabilities, net of current portion	5,525,562	—
Subordinated notes	—	7,331,254
Senior Convertible notes	13,651,000	—
Subordinated Convertible note	10,355,681	—
Earnout Liability	12,810,000	—
Warrant liability	1,991,503	562,244
Deferred rent	—	57,741
Total noncurrent liabilities	46,600,801	15,652,272
Total liabilities	53,691,070	22,224,244
Commitments and contingencies		
Series B redeemable convertible preferred stock, $0.0001 par value, 7,610,700 shares authorized; 7,288,333 shares issued and outstanding at December 31, 2021; liquidation preference of $26,237,999 at December 31, 2021	—	12,389,547
Series A redeemable convertible preferred stock, $0.0001 par value, 26,250 shares authorized; 26,245 shares issued and outstanding at December 31, 2021; liquidation preference of $26,245,000 at December 31, 2021	—	26,245,000
Stockholders' deficit:		
Common stock, $0.0001 par value, 100,000,000 and 36,038,535 shares authorized at December 31, 2022 and 2021, respectively; 16,041,464 and 24,566,386 shares issued and outstanding at December 31, 2022 and 2021, respectively	1,604	2,456
Additional paid-in capital	190,298,562	150,425,960
Accumulated deficit	(210,794,595)	(203,649,275)
Total stockholders' deficit	(20,494,429)	(53,220,859)
Total liabilities, redeemable convertible preferred stock, and stockholders' deficit	$ 33,196,641	$ 7,637,932

See notes to consolidated financial statements.

PROSOMNUS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS
For the years ended December 31, 2022 and 2021

	2022	2021
Revenue	$ 19,393,343	$ 14,074,649
Cost of revenue	9,127,338	6,764,319
Gross profit	10,266,005	7,310,330
Operating expenses		
Research and development	2,981,271	1,889,208
Sales and marketing	8,865,328	5,776,084
General and administrative	9,894,899	4,467,576
Total operating expenses	21,741,498	12,132,868
Net Loss from Operations	(11,475,493)	(4,822,538)
Other income (expense)		
Interest expense	(6,119,806)	(3,245,220)
Gain on PPP loans	—	2,281,262
Change in fair value of earnout liability	9,260,000	—
Change in fair value of debt	553,235	—
Change in fair value of warrant liability	3,234,586	(190,911)
Loss on extinguishment of debt	(2,597,842)	—
Total other income (expense)	4,330,173	(1,154,869)
Net loss before income taxes	(7,145,320)	(5,977,407)
Provision for income taxes	—	—
Net loss	$ (7,145,320)	$ (5,977,407)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.71)	$ (1.51)
Weighted average shares used in computing net loss per share attributable to common stockholders, basic and diluted	10,021,632	3,957,783

See notes to consolidated financial statements.

PROSOMNUS, INC.

CONSOLIDATED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT
For the years ended December 31, 2022 and 2021

	Redeemable Convertible Preferred Stock										
	Series B		Series A		Common Stock		Class A Common Stock		Additional Paid-In	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	Deficit
Balance as of January 1, 2021	7,288,333	$ 12,389,547	26,245	$ 26,245,000	24,184,697	$ 2,418	—	$ —	$ 150,421,286	$ (197,671,868)	$ (47,248,164)
Vesting of restricted stock awards	—	—	—	—	381,689	38	—	—	(38)	—	—
Stock-based compensation expense	—	—	—	—	—	—	—	—	4,712	—	4,712
Net loss	—	—	—	—	—	—	—	—	—	(5,977,407)	(5,977,407)
Balance as of December 31, 2021	7,288,333	12,389,547	26,245	26,245,000	24,566,386	2,456	—	—	150,425,960	(203,649,275)	(53,220,859)
Vesting of options	—	—	—	—	854,507	85	—	—	2,156,915	—	2,157,000
Issuance of Series A Preferred - Convertible Bridge Notes	—	—	13,081	—	—	—	—	—	13,080,756	—	13,080,756
Issuance of Series A Preferred – ProSomnus Common Holders	—	—	5,945	—	—	—	—	—	—	—	—
Issuance of Series B Preferred Stock for Warrants	161,112	16		—	—	—	—	—	579,984	—	579,984
Merger Recapitalization - Preferred	(7,449,445)	(12,389,563)	(45,271)	(26,245,000)	—	—	7,208,865	721	38,635,975	—	38,636,696
Merger Recapitalization - Common	—	—	—	—	(25,420,893)	(2,541)	4,084,418	408	—	—	(2,132)
Issuance of Common Stock - services	—	—	—	—	—	—	716,223	72	7,159,090	—	7,159,162
Issuance costs - ProSomnus Inc.	—	—	—	—	—	—	—	—	(12,640,679)	—	(12,640,679)
Conversion of LAAA Founder Common Stock	—	—	—	—	—	—	1,054,390	105	(105)	—	—
Issuance of Common Stock - Lakeshore Public Stockholders	—	—	—	—	—	—	820,722	82	(82)	—	—
Issuance of Common Stock - PIPE Equity	—	—	—	—	—	—	1,830,133	183	10,249,817	—	10,250,000
Issuance of Common Stock - PIPE Debt SPA Shares	—	—	—	—	—	—	326,713	33	478,834	—	478,867
Assumption of SPAC Assets and Liabilities	—	—	—	—	—	—	—	—	2,242,097	—	2,242,097
Earn-out liability	—	—	—	—	—	—	—	—	(22,070,000)	—	(22,070,000)
Net loss	—	—	—	—	—	—	—	—	—	(7,145,320)	(7,145,320)
Balance as of December 31, 2022	—	$ —	—	$ —	—	$ —	16,041,464	$ 1,604	$ 190,298,561	$ (210,794,595)	$ (20,494,429)

See notes to consolidated financial statements.

PROSOMNUS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS
For the years ended December 31, 2022 and 2021

	2022	2021
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (7,145,320)	$ (5,977,407)
Adjustments to reconcile net loss to net cash used in operating activities:		
Gain on PPP loans	—	(2,281,262)
Depreciation	424,359	827,568
Amortization of finance right-of-use asset	772,870	—
Amortization of operating right-of-use asset	207,464	—
Noncash interest	5,004,260	710,444
Amortization of debt discount	145,228	140,544
Bad debt expense	138,850	105,256
Stock-based compensation	2,157,000	4,712
Change in Earnout Liability	(9,260,000)	—
Change in fair value of debt	(553,235)	—
Change in fair value of warrant liability	(3,234,586)	190,911
Loss on extinguishment of debt	2,597,842	—
Changes in operating assets and liabilities:		
Accounts receivable	(883,016)	(745,714)
Inventory	(261,176)	(167,836)
Prepaid expenses and other current assets	(1,745,180)	26,174
Other assets	(108,116)	(92,414)
Accounts payable	1,145,924	180,655
Accrued expenses	517,277	2,443,435
Operating lease liability	(159,348)	—
Net cash used in operating activities	**(10,238,905)**	**(4,634,934)**
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	(1,353,662)	(301,302)
Net cash used in investing activities	**(1,353,662)**	**(301,302)**
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from PIPE Equity Financing	9,450,000	—
Proceeds from SPAC Trust	4,920,826	—
Issuance costs paid in closings	(8,243,247)	—
Proceeds from Issuance of Convertible Notes	27,452,121	—
Proceeds from line of credit	24,362,059	17,543,950
Repayments of line of credit	(24,949,874)	(16,956,135)
Proceeds from issuance of subordinated notes	375,000	2,765,000
Repayments of subordinated notes	(75,000)	—
Principal payments on finance lease obligations	(1,222,270)	(777,431)
Principal payments on equipment financing obligation	(56,126)	(49,662)
Proceeds from Paycheck Protection Program loans	—	1,003,112
Proceeds from subordinated loan and security agreement	—	1,955,067
Repayments of subordinated loan and security agreement	(10,652,314)	(602,637)
Proceeds from issuance of unsecured subordinated promissory notes	5,260,908	—
Repayments of unsecured subordinated promissory notes	(613,956)	—
Net cash provided by financing activities	**26,008,126**	**4,881,264**
Net increase (decrease) in cash and cash equivalents	14,415,559	(54,972)
Cash and cash equivalents at beginning of year	1,500,582	1,555,554
Cash and cash equivalents at end of year	$ 15,916,141	$ 1,500,582
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 1,189,279	$ 648,322
Cash paid for franchise taxes	$ 6,480	$ 7,652
Supplemental disclosure of noncash investing and financing activities:		
Acquisition of property and equipment through capital leases	$ —	$ 985,857
Acquisition of property and equipment through finance financing	$ 2,233,834	$ —
Addition of ROU assets from finance lease modification	$ 239,000	$ —
Conversion of Bridge Notes into Equity	$ 13,080,756	
Issuance of stock for repayment of Subordinated Loan and Security agreement and Bridge Loan (secured subordinated loan)	$ 800,000	
Issuance of Subordinated convertible notes for repayment of Subordinated Loan and Security agreement and Bridge Loan (secured subordinated loan)	$ 2,547,879	
Issuance of common stock warrants in connection with senior and subordinated convertible notes	$ 1,991,503	$ —
Issuance of common stock in exchange for investment banking services	$ 7,159,162	$ —
Issuance of redeemable convertible preferred stock warrant in connection with subordinated loan and security agreement	$ —	$ 143,333

See notes to consolidated financial statements.

PROSOMNUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
For the years ended December 31, 2022 and 2021

NOTE 1 — DESCRIPTION OF THE BUSINESS

Company Organization

ProSomnus, Inc., and its wholly owned subsidiaries, ProSomnus Holdings, Inc., ProSomnus Sleep Technologies, Inc. (collectively, the "Company") is an innovative medical technology company that develops, manufactures, and markets its proprietary line of precision intraoral medical devices for treating and managing patients with obstructive sleep apnea ("OSA").

The Company is located in Pleasanton, California and was incorporated as Delaware company on May 3, 2022. Its accounting predecessor company, Sleep Technologies, Inc. was incorporated in Delaware on March 2, 2016.

On December 6, 2022, Lakeshore Acquisition I Corp. ("Lakeshore") consummated a series of transactions that resulted in the combination (the "Business Combination") of Lakeshore with ProSomnus Holdings, Inc. and its wholly-owned subsidiary, Prosomnus Sleep Technologies, Inc., pursuant to an Agreement and Plan of Merger, dated May 9, 2022. Pursuant to the Merger Agreement, Lakeshore merged with and into ProSomnus Holdings, and changed its name to ProSomnus, Inc.

The transaction was accounted for as a reverse recapitalization with ProSomnus Sleep Technologies, Inc. being the accounting acquirer and Lakeshore as the acquired company for accounting purposes. Accordingly, all historical financial information presented in the consolidated financial statements represents the accounts of ProSomnus Sleep Technologies, Inc.

Prior to the Business Combination, Lakeshore's units, public shares, and public warrants were listed on The Nasdaq Global Market under the symbols "LAAU," "LAAA," and "LAAW," respectively. On December 6, 2022, the Company's Class A common stock and public warrants began trading on Nasdaq, under the symbols "OSA" and "OSAAW," respectively.

NOTE 2 – BASIS OF ACCOUNTING AND SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying consolidated financial statements were prepared on the accrual basis of accounting in accordance with principles generally accepted in the United States of America ("U.S. GAAP").

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiary. Intercompany balances and transactions have been eliminated in consolidation.

Liquidity and Management's Plans

The Company has incurred recurring losses from operations and recurring negative cash flows from operating activities. At December 31, 2022, the Company had a working capital of $14.2 million and cash and cash equivalents of $15.9 million. The Company expects to continue to incur net losses for the foreseeable future as it continues the development of its products.

On December 6, 2022, on consummation of the Busines Combination, we received $4.92 million of cash held in Lakeshore's trust account from its initial public offering, $10.25 million of cash in connection with the PIPE Equity financing and approximately $30 million in proceeds from the Convertible Notes offering. These proceeds were used to pay transaction expenses and other liabilities of Lakeshore, pay certain transaction expenses of ProSomnus, and pay off approximately $11.53 million in debt of ProSomnus at closing, with the remaining being deposited in ProSomnus' cash account.

Based on cash flow projections from operating and financing activities and existing balance of cash and cash equivalents and investments, management is of the opinion that the Company has sufficient funds for sustainable operations, and it will be able to meet its payment obligations from operations and debt related commitments for at least one year from the issuance date of these financial statements. Based on the above considerations, the Company's consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and liquidation of liabilities during the normal course of operations.

The Company's ability to continue as a going concern is dependent on management's ability to control operating costs and maintain revenue growth forecast. Management believes there is not substantial doubt about the ability of the Company to meet its obligations and operations for twelve months after the issuance of the consolidated financial statements.

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue and expenses, and disclosure of contingent assets and liabilities. Actual results could differ from these estimates, and such differences could materially affect the results of operations reported in future periods. The Company's most significant estimates in these consolidated financial statements relate to the fair value of Senior and Subordinated convertible notes, fair value of Earnout liability, fair value of warrants, provision for doubtful accounts receivable, the warranty and earned discount accruals, future revenue estimates used to calculate the current and long-term portions due under the subordinated loan agreement, the effective interest rates of the subordinated loan agreement, measurement of tax assets and liabilities and stock-based compensation.

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to a concentration of credit risk principally consist of accounts receivable and cash.

The Company sells its products to customers primarily in North America and Europe. To reduce credit risk, management performs periodic credit evaluations of its customers' financial condition. No customers exceeded more than 10% of the Company's revenue or accounts receivables as of and for the years ended December 31, 2022 and 2021.

The Company maintains its cash in bank accounts which, at times, may exceed federally insured limits as guaranteed by the Federal Deposit Insurance Corporation ("FDIC"). The Company believes its credit risk is mitigated due to the high quality of the banks in which it places its deposits.

Fair Value of Financial Instruments

The accounting standard for fair value measurements provides a framework for measuring fair value and requires expanded disclosures regarding fair value measurements. Fair value is defined as the price that would be received for an asset or the exit price that would be paid to transfer a liability in the principal or most advantageous market in an orderly transaction between market participants on the measurement date.

This accounting standard establishes a fair value hierarchy, which requires an entity to maximize the use of observable inputs, where available. The following summarizes the three levels of inputs that may be used to measure fair value:

Level 1 Inputs — The valuation is based on quoted prices in active markets for identical instrument.

Level 2 Inputs — The valuation is based on observable inputs such as quoted prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active, and model — based valuation techniques for which all significant assumptions are observable in the market.

Level 3 Inputs — The valuation is based on unobservable inputs that are supported by minimal or *no* market activity and that are significant to the fair value of the instrument. Level *3* valuations are typically performed using pricing models, discounted cash flow methodologies, or similar techniques that incorporate management's own estimates of assumptions that market participants would use in pricing the instrument, or valuations that require significant management judgment or estimation.

Changes in fair value measurements categorized within Level 3 of the fair value hierarchy are analyzed each period based on changes in estimates or assumptions and recorded as appropriate.

Change in Fair Value of Senior and Subordinated Convertible Notes

Under the fair value election as prescribed by ASC 815, the Company will record changes in fair value through the consolidated statement of operations as a fair value adjustment of the convertible debt each reporting period, with the portion of the change that results from a change in the instrument-specific credit risk recorded separately in other comprehensive income, if applicable. The Company has also elected not to separately present interest expense related to the Senior and Subordinated Promissory Notes and the

entire change in fair value of the instrument will be recorded as a fair value adjustment of convertible debt within the consolidated statement of operations.

As a result of the merger transaction, the company assumed an Earn-out liability, which is remeasured each reporting period. Given the unobservable nature of the inputs, the fair value measurement of the deferred earn-out is deemed to use Level 3 inputs. The Earn-out liability was accounted for as a liability as of the date of the merger transaction and will be remeasured to fair value until the Earnout Triggering Events are met.

The Company believes the carrying amounts of financial instruments including cash and cash equivalents, accounts receivable (net of allowance for doubtful accounts), accounts payable, and revolving line of credit approximate fair value due to their short-term nature.

Comprehensive Income

Comprehensive income is defined as the change in equity (net assets) of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. It consists of net income and other gains and losses affecting stockholders' equity that, under U.S. GAAP, are excluded from net income. Comprehensive income is equal to the net income for the years ended December 31, 2022 and 2021.

Cash and Cash Equivalents

The company considers all demand deposits with an original maturity to the Company of 90 days or less as cash and cash equivalents. The Company places its cash and cash equivalents with high credit-quality financial institutions. As of years ended December 31, 2022 and 2021, the Company had $15.9 million and $1.5 million of cash, respectively, and there were no cash equivalents.

Accounts Receivable

The Company reports accounts receivables at net realizable value. The Company has not historically assessed finance charges on past due accounts, but retains the right to do so. The allowance for doubtful accounts is estimated based on historical write-off percentages and management's assessment of specific past due or delinquent customer accounts. The delinquency status of customers is determined by reference to contractual terms. Doubtful accounts are written off against the allowance for doubtful accounts after collection efforts have been exhausted and are recorded as recoveries of bad debts, if subsequently collected. The allowance for doubtful accounts amounted to $162,635 and $100,000 as of December 31, 2022 and 2021, respectively. All accounts receivable are primarily from customers located in North America and Europe.

Inventory

Inventory is recorded at the lower of cost or net realizable value under the first-in, first-out method of accounting. Inventories primarily consist of purchased raw materials. The Company regularly reviews whether the net realizable value of its inventory is lower than its carrying value. If the valuation shows that the net realizable value is lower than the carrying value, the Company takes a charge to cost of revenue and directly reduces the carrying value of the inventory. Indicators that could result in inventory write-downs include damaged or slow-moving materials and supplies.

Property and Equipment

Property and equipment are stated at cost, less accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful lives of the related assets. Estimated useful lives are as follows:

Manufacturing equipment.	3 to 7 years
Computers and software	3 years
Furniture.	7 years
Leasehold Improvements	Shorter of remaining lease term or estimated useful life

Maintenance and repairs are charged to operations as incurred.

Through December 31, 2021, equipment capitalized under capital lease obligations was included in property and equipment. Property and equipment capitalized under capital lease obligations were amortized using a straight-line method over the shorter of the life of the lease or the useful life of the asset, which ranges from three to seven years, and was included in depreciation expense in the consolidated statements of operations. On January 1, 2022 the Company adopted Accounting Standards Update ("ASU") 2016-02, *Leases* ("ASC 842"), which impacted the classification of equipment formerly capitalized under capital lease obligations. The equipment related

to capital leases, now finance leases, have been reclassified from property and equipment to right-of-use assets on the consolidated balance sheet.

Occasionally, the Company enters into finance lease arrangements for various machinery, equipment, computer-related equipment, or software. The Company records amortization of assets leased under finance lease arrangements.

Long-lived Assets

The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset many not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future undiscounted cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured at the amount by which the carrying amount of the asset exceeds the fair value of the assets. Assets to be disposed of are reported at the lower of carrying amount or the fair value less costs to sell. No such impairments have been identified during the years ended December 31, 2022 and 2021.

Redeemable Convertible Preferred Stock

All Series A and Series B redeemable convertible preferred stock were converted into common shares of the Company on close of the merger transaction in December 2022. Prior to the merger transaction, the Company recorded all shares of redeemable convertible preferred stock at their respective issuance price, less issuance costs on the dates of issuance. The redeemable convertible preferred stock was presented outside of stockholders' deficit in the consolidated balance sheets. When redeemable convertible preferred stock was considered either then currently redeemable or probable of becoming redeemable, the Company selected a policy to recognize changes in the redemption value immediately, as they would have occured and adjust the carrying value of redeemable convertible preferred stock to the greater of the redemption value at the end of each reporting period or the initial carrying amount.

Senior and Subordinated Convertible Notes

The Company accounts for its derivatives in accordance with, ASC 815-10, Derivatives and Hedging, or ASC 815-15, Embedded Derivatives, depending on the nature of the derivative instrument. ASC 815 requires each contract that is not a derivative in its entirety be assessed to determine whether it contains embedded derivatives that are required to be bifurcated and accounted for as a derivative financial instrument. The embedded derivative is bifurcated from the host contract and accounted for as a freestanding derivative if the combined instrument is not accounted for in its entirety at fair value with changes in fair value recorded in earnings, the terms of the embedded derivative are not clearly and closely related to the economic characteristics of the host contract, and a separate instrument with the same terms as the embedded derivative would qualify as a derivative instrument. Embedded derivatives are measured at fair value and remeasured at each subsequent reporting period, and recorded within convertible notes, net on the accompanying Consolidated Balance Sheets and changes in fair value recorded in other expense within the Consolidated Statements of Operations. Debt discounts under these arrangements are amortized to interest expense using the interest method over the earlier of the term of the related debt or their earliest date of redemption.

Upon the consummation of the Business Combination, the Company issued Senior and Subordinated Convertible Notes. The Company analyzed various redemption, conversion and settlement features, and other derivative instrument features of these Convertible Notes offering.

- The Company identified that the (i) redemption features, (ii) Lender's Optional Conversion feature, (iii) Lender's Optional Conversion Upon Merger Event feature and (iv) Additional interest rate upon certain events feature meet the definition of a derivative. (See Footnote 8 – Debt). The Company analyzed the scope exception for all the above features under ASC 815-10-15-74(a).

- Based on the further analysis, the Company identified that the (i) Lender's Optional Conversion feature, (ii) Lender's Optional Conversion Upon Merger Event feature and (iii) Additional interest rate upon certain events feature, do not meet the settlement criteria to be considered indexed to equity. The Company concluded that each of these features should be classified as a derivative liability measured at fair value with the changes in Fair Value in the Consolidated Statement of Operations.

- The Company also identified that the redemption features are settled in cash and do not meet the indexed to equity and the equity classification scope exception, thus, they must be bifurcated from the convertible notes and accounted for separately at fair value on a recurring basis reflecting the changes in Fair Value in the Consolidated Statement of Operations.

The Company determined the Notes contained multiple embedded derivatives that are required to be bifurcated, two of which are conversion features.

As per ASC 815, if there is a conversion feature that is required to be bifurcated, the cash conversion feature and beneficial conversion feature guidance is not applicable to such conversion feature and the fair value election is allowable provided the debt was not issued at a substantial premium. The Company concluded that the Senior and Subordinated Convertible Notes were not issued at a premium and hence the Company elected the fair value option under ASC 815-15-25. The Company elected to record changes in fair value through the Consolidated Statement of Operations as a fair value adjustment of the convertible debt each reporting period (with the portion of the change that results from a change in the instrument-specific credit risk recorded separately in other comprehensive income, if applicable). The Company has also elected not to separately present interest expense related to the Senior and Subordinated Promissory Notes and the entire change in fair value of the instrument will be recorded as a fair value adjustment of convertible debt within the Consolidated Statement of Operations. Thus, the multiple embedded derivatives do not need to be separately bifurcated and fair valued. The Senior and Subordinated Convertible Notes are reflected at their respective fair values on the Consolidated Balance Sheet at December 31, 2022.

Warrants

The Company accounts for warrants as either equity-classified or liability-classified instruments based on an assessment of the warrant's specific terms and applicable authoritative guidance in Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 480, *Distinguishing Liabilities from Equity* ("ASC 480") and ASC 815, *Derivatives and Hedging* ("ASC 815"). The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, meet the definition of a liability pursuant to ASC 480, and whether the warrants meet all of the requirements for equity classification under ASC 815, including whether the warrants are indexed to the Company's own common stock, among other conditions for equity classification. This assessment, which requires the use of professional judgment, is conducted at the time of warrant issuance and as of each subsequent reporting period end date while the warrants are outstanding.

For issued or modified warrants that meet all of the criteria for equity classification, the warrants are required to be recorded as a component of additional paid-in capital at the time of issuance. For issued or modified warrants that do not meet all the criteria for equity classification, the warrants are required to be recorded at their initial fair value on the date of issuance, and then remeasured at fair value at each balance sheet date thereafter. Changes in the estimated fair value of the warrants are recognized as a non-cash other income or expense on the consolidated statements of operations.

Warranty

The Company offers a warranty guaranteeing the fit and finish of their intraoral devices for three years from the date of initial sale, as well as a guarantee for the unlimited remaking of arches. The accrual for warranty claims and unlimited arch remakes totaled $269,496 and $217,244 at December 31, 2022 and 2021, respectively, and these amounts are recorded in accrued expenses on the consolidated balance sheets.

Revenue Recognition

The Company creates customized precision milled intraoral devices. When devices are sold, they include an assurance-type warranty guaranteeing the fit and finish of the product for a period of 3 years from the date of sale.

The Company recognizes revenue upon meeting the following criteria:

- Identifying the contract with a customer: Customers submit authorized prescriptions and dental impressions to the Company. Authorized prescriptions constitute the contract with customers.

- Identifying the performance obligations within the contract: The sole performance obligation is the shipment of a completed customized intraoral device.

- Determining the transaction price: Prices are determined by standardized pricing sheets and adjusted for estimated returns, discounts, and allowances.

- Allocating the transaction price to the performance obligations: The full transaction price is allocated to the shipment of the completed intraoral device as it is the only element in the transaction.

- Recognizing revenue as the performance obligation is satisfied: revenue is recognized upon transfer of control which occurs upon shipment of the product.

The Company does not require collateral or any other form of security from customers. Inbound shipping and handling costs related to sales are billed to customers. We charge for inbound shipping/handling and the costs are classified as Cost of Revenue. Outbound shipping costs are not billed to customers and are included in sales and marketing expenses. Taxes collected from customers and remitted to governmental authorities are excluded from revenue.

Standalone selling price for the various intraoral device models are determined using the Company's standard pricing sheet. The Company invoices customers upon shipment of the product and invoices are due within 30 days. Amounts that have been invoiced are recorded in accounts receivable and revenue as all revenue recognition criteria have been met. Given the nominal value of each transaction, the Company does not offer a financing component related to its revenue arrangements.

Cost of Revenue

Cost of revenue consists primarily of materials and the costs related to the production of the intra-oral device, including employee compensation, other employee-related expenses and allocable manufacturing overhead costs. The Company has a policy to classify initial recruiting, onboarding and training costs of new manufacturing employees as part of research and development expenses in the consolidated statements of operations. Such costs totaled $211,218 and $144,775 for the years ended December 31, 2022 and 2021, respectively.

The Company utilizes the practical expedient which permits expensing of costs to obtain a contract when the expected amortization period is one year or less, which typically results in expensing commissions paid to employees. The Company expenses sales commissions paid to employees as revenue are recognized.

Research and Development

Research and development costs are charged to operations as incurred.

Advertising

Advertising costs are expensed as incurred and totaled $100,319 and $87,764 for the years ended December 31, 2022 and 2021, respectively.

Stock-Based Compensation

The Company's stock-based compensation expense is recognized based on the estimated fair value of the restricted stock awards on the date of grant. The grant-date fair value of all stock-based payment awards is recognized as employee compensation expense on a straight-line basis over the requisite service period. The Company recognizes forfeitures of restricted stock awards as they occur.

Leases

The Company assesses at contract inception whether a contract is, or contains, a lease. Generally, the Company determines that a lease exists when (1) the contract involves the use of a distinct identified asset, (2) the Company obtains the right to substantially all economic benefits from use of the asset, and (3) the Company has the right to direct the use of the asset. A lease is classified as a finance lease when one or more of the following criteria are met: (1) the lease transfers ownership of the asset by the end of the lease term, (2) the lease contains an option to purchase the asset that is reasonably certain to be exercised, (3) the lease term is for a major part of the remaining useful life of the asset, (4) the present value of the lease payments equals or exceeds substantially all of the fair value of the asset or (5) the asset is of such a specialized nature that it is expected to have no alternative use to the lessor at the end of the lease term. A lease is classified as an operating lease if it does not meet any of these criteria.

At the lease commencement date, the Company recognizes a right-of-use asset and a lease liability for all leases, except short- term leases with an original term of 12 months or less. The right-of-use asset represents the right to use the leased asset for the lease term. The lease liability represents the present value of the lease payments under the lease. The right-of-use asset is initially measured at cost, which primarily comprises the initial amount of the lease liability, less any lease incentives received. All right-of-use assets are periodically reviewed for impairment in accordance with standards that apply to long-lived assets. The lease liability is initially measured at the present value of the lease payments, discounted using an estimate of the Company's incremental borrowing rate for a collateralized loan with the same term as the underlying leases for operating leases and the implied rate in the lease agreement for finance leases.

Lease payments included in the measurement of lease liabilities consist of (1) fixed lease payments for the noncancelable lease term, (2) fixed lease payments for optional renewal periods where it is reasonably certain the renewal option will be exercised, and (3) variable lease payments that depend on an underlying index or rate, based on the index or rate in effect at lease commencement. The

Company's real estate operating lease agreement requires variable lease payments that do not depend on an underlying index or rate established at lease commencement. Such payments and changes in payments are recognized in operating expenses when incurred.

Lease expense for operating leases consists of the fixed lease payments recognized on a straight-line basis over the lease term plus variable lease payments as incurred. Lease expense for finance leases consists of the amortization of assets obtained under finance leases on a straight-line basis over the lease term and interest expense on the lease liability based on the discount rate at lease commencement.

Income Taxes

The Company accounts for income taxes under an asset and liability approach. Deferred income taxes reflect the impact of temporary differences between assets and liabilities recognized for financial reporting purposes and such amounts recognized for income tax reporting purposes as well as net operating loss carryforwards and tax credit carryforwards. Valuation allowances are provided when necessary to reduce deferred tax assets to an amount that is more likely than not to be realized.

Significant judgment may be required in determining any valuation allowance recorded against deferred tax assets. In assessing the need for a valuation allowance, the Company considers all available evidence, including past operating results, estimates of future taxable income and the feasibility of tax planning strategies. In the event that the Company changes its determination as to the amount of deferred tax assets that is more likely than not to be realized, the Company will adjust its valuation allowance with a corresponding impact to the provision for income taxes in the period in which such determination is made.

The Company follows authoritative guidance regarding uncertain tax positions. The guidance requires that realization of an uncertain income tax position must be more likely than not (i.e., greater than 50% likelihood of receiving a benefit) before it can be recognized in the consolidated financial statements. The guidance further prescribes the benefit to be realized assumes a review by taxing authorities having all relevant information and applying current conventions.

The guidance also clarifies the consolidated financial statements classification of tax related penalties and interest and sets forth disclosures regarding unrecognized tax benefits. The Company recognizes potential accrued interest and penalties related to unrecognized tax benefits as income tax expense.

Net Loss per Share Attributable to Common Stockholders

Basic net loss per share attributable to common stockholders is calculated by dividing the net loss attributable to common stockholders by the weighted average number of shares of common stock outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders, since the effects of potentially dilutive securities are antidilutive.

Segment Reporting

Operating segments are defined as components of an entity for which separate financial information is available and that is regularly reviewed by the Chief Operating Decision Maker ("CODM") in deciding how to allocate resources to an individual segment and in assessing performance. The Company's CODM is its Chief Executive Officer and Chief Financial Officer. The Company has determined that it operates in one operating segment and one reportable segment, as the CODM reviews financial information presented on a consolidated basis for purposes of making operating decisions, allocating resources, and evaluating financial performance.

Recent Accounting Pronouncements

On January 1, 2022, the Company adopted Accounting Standards Update ("ASU") 2016-02, *Leases* (ASC 842), which superseded previous guidance related to accounting for leases within Topic 842, *Leases*. The Company elected the practical expedient provided under ASU 2018-11, *Leases (ASC 842) Targeted Improvements,* which amended ASU 2016-02 to provide entities an optional transition practical expedient to adopt the new standard with a cumulative effect adjustment as of the beginning of the year of adoption with prior year comparative financial information and disclosures remaining as previously reported. As a result, no adjustments were made to the consolidated balance sheet prior to January 1, 2022 and amounts are reported in accordance with historical accounting under Topic 840, while the consolidated balance sheet as of December 31, 2022 is presented under Topic 842.

The Company elected the package of practical expedients permitted under the transition guidance, which allowed it to carry forward historical lease classification, assessment on whether a contract was or contains a lease, and assessment of initial direct costs for any leases that existed prior to January 1, 2022. The Company also elected to combine its lease and non-lease components and to keep leases

with an initial term of 12 months or less off the consolidated balance sheet and recognize the associated lease payments in the consolidated statements of operations on a straight-line basis over the lease term.

Adoption of the new standard resulted in the recording of right of use assets and operating lease liabilities of $406,551 and $464,291, respectively, as of January 1, 2022. Additionally, upon adoption of the new standard, the Company reclassified the equipment of $2,349,591 related to capital leases to right of use assets. Finance lease liabilities of $1,826,973 were reclassified from capital lease obligation. The transition did not have a material impact on the Company's consolidated results of operations, cash flows or liquidity measures.

In August 2020, the Financial Accounting Standards Board ("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) ("ASU 2020-06") to simplify accounting for certain financial instruments. ASU 2020-06 eliminates the current models that require separation of beneficial conversion and cash conversion features from convertible instruments and simplifies the derivative scope exception guidance pertaining to equity classification of contracts in an entity's own equity. The new standard also introduces additional disclosures for convertible debt and freestanding instruments that are indexed to and settled in an entity's own equity. ASU 2020-06 amends the diluted earnings per share guidance, including the requirement to use the if-converted method for all convertible instruments. ASU 2020-06 is effective January 1, 2024 and should be applied on a full or modified retrospective basis, with early adoption permitted beginning on January 1, 2021. The Company is currently assessing the impact, if any, that ASU 2020-06 would have on its financial position, results of operations or cash flows.

In December 2019, the FASB issued ASU 2019-12, Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes ("ASU 2019-12"), as part as part of its overall simplification initiative to reduce costs and complexity of applying accounting standards while maintaining or improving the usefulness of the information provided to users of financial statements. Amendments include removal of certain exceptions to the general principles of ASC 740, Income Taxes and simplification in several other areas such as accounting for a franchise tax (or similar tax) that is partially based on income. ASU 2019-12 is effective for public business entities for annual reporting periods beginning after December 15, 2020, and interim periods within those reporting periods. The impact to the company is immaterial.

NOTE 3 - MERGER AND REVERSE RECAPITALIZATION

Business Combination Transaction

On May 9, 2022, Lakeshore and ProSomnus Holdings, Inc. executed the Merger Agreement. Pursuant to the Merger Agreement, the business combination was effected in two steps: (i) upon approval and adoption of the Merger Agreement by the shareholders of Lakeshore, Lakeshore reincorporated to the State of Delaware by merging with and into LAAA Merger Corp., a Delaware corporation and wholly-owned subsidiary of Lakeshore ("**PubCo**"), with PubCo surviving as the publicly traded entity (the "**Reincorporation Merger**"); and (ii) immediately after the Reincorporation Merger, LAAA Merger Sub Inc., a Delaware corporation and wholly-owned subsidiary of PubCo ("**Merger Sub**"), merged with and into ProSomnus Holdings, Inc., with ProSomnus, surviving as a wholly-owned subsidiary of PubCo (the "**Acquisition Merger**"). The Merger Agreement was by and among Lakeshore, PubCo, Merger Sub, ProSomnus and HGP II, LLC, as the representative of the stockholders of ProSomnus ("**Stockholders' Representative**"), and RedOne Investment Limited, as the representative of the shareholders of Lakeshore. The Reincorporation Merger and the Acquisition Merger are collectively referred to herein as the "**Business Combination**" and the resulting execution of the transaction is herein referred to as "**Merger Transaction**". References to "**Legacy ProSomnus**" refer to ProSomnus Holdings, Inc. and its consolidated subsidiaries prior to the consummation of the Merger.

On December 6, 2022, Lakeshore consummated a series of transactions that resulted in the combination (the "**Business Combination**") of Lakeshore with ProSomnus Holdings, Inc., a Delaware Corporation ("**ProSomnus Holdings**") pursuant to the previously announced Agreement and Plan of Merger, dated May 9, 2022 (the "**Merger Agreement**"), by and among Lakeshore, Merger Sub, RedOne Investment Limited ("**Sponsor**"), as purchaser representative, Stockholders' Representative, and ProSomnus Holdings, following the approval at the extraordinary general meeting of the shareholders of Lakeshore held on December 2, 2022 (the "**Special Meeting**"). Pursuant to the Merger Agreement, Lakeshore merged with and into PubCo, Merger Sub merged with and into ProSomnus Holdings, and Surviving Pubco changed its name to ProSomnus, Inc., resulting in ProSomnus Holdings being a wholly owned subsidiary of ProSomnus, Inc.

Simultaneous with the closing of the Business Combination, the Company also completed a series of private financings, issuing and selling 1,025,000 shares of its common stock in a private placement to certain PIPE investors (the "**Equity PIPE Offering**"), entering into non-redemption agreements with holders of an aggregate of approximately 0.48 million public shares of common stock of Lakeshore, and issuing an aggregate of $16.96 million principal value senior secured convertible notes (the "**Senior convertible notes**") and an aggregate of $17.45 million principal value subordinated secured convertible notes (the "**Subordinated convertible notes**") to certain investors pursuant to previously announced Senior Securities Purchase Agreement and Subordinated Securities Purchase

Agreement, each dated August 26, 2022. Pursuant to the terms of the Merger Agreement, the total consideration for the Business Combination and related transactions (the "**Merger Consideration**") was approximately $113 million. In connection with the Special Meeting, holders of 2,380,246 shares of Lakeshore ordinary shares sold in its initial public offering exercised their right to redeem those shares for cash prior to the redemption deadline of November 30, at a price of $10.238 per share, for an aggregate payment from Lakeshore's trust account of approximately $24.37 million.

As a result of the Reincorporation Merger and the Business Combination, holders of Lakeshore ordinary shares automatically received common stock of the Company, and holders of Lakeshore warrants automatically received warrants of the Company with substantively identical terms. At the Closing of the Business Combination, 1,054,390 ordinary shares of Lakeshore owned by the Sponsor, which we refer to as the founder shares, automatically converted into an equal number of shares of the Company common stock, and 196,256 Private Placement Warrants held by the Sponsor, each exercisable for one ordinary share of Lakeshore at $11.50 per share, automatically converted into warrants to purchase one share of Surviving Pubco common stock at $11.50 per share with substantively identical terms. An aggregate of 4,597,180 warrants were issued to holders of Lakeshare founder shares, and private and public warrant holders, as a result of the Business Combination, see Footnote 9 – Common Stock Warrants.

Additionally, Legacy ProSomnus stockholders (other than holders of ProSomnus Subordinated Debt) are entitled to receive up to 3.0 million Earn-out shares in three tranches:

- the first tranche of 1.0 million Earn-out shares will be issued when the volume-weighted average price per share of PubCo Common Stock is $12.50 or greater for 20 trading days in any consecutive 30 trading day period commencing 6 months after the Closing and ending at the third anniversary of the Closing;

- the second tranche of 1.0 million Earn-out shares will be issued when the volume-weighted average price per share of PubCo Common Stock is $15.00 or greater for 20 trading days in any consecutive 30 trading day period commencing 6 months after the Closing and ending at the third anniversary of the Closing; and

- the third tranche of 1.0 million Earn-out shares will be issued when the volume-weighted average price per share of PubCo Common Stock is $17.50 or greater for 20 trading days in any consecutive 30 trading day period commencing 6 months after the Closing and ending at the third anniversary of the Closing.

The Earn-out shares will be allocated among Legacy ProSomnus's stockholders in proportion to the number of shares issued to them at the closing that continue to be held by them.

Concurrently with the execution of the Merger Agreement, in May and September 2022, the Company and certain holders of the Bridge Loans executed a conversion addendum. Upon notice of the Business Combination Agreement, the holders of the Bridge Loans had up to 10 days to elect to convert into Series A Redeemable Convertible Preferred Stock. Immediately prior to the closing of the Business Combination, the Bridge Loans automatically converted into the number of Series A Redeemable Convertible Preferred Stock as equal to the repayment amount of the Bridge Loans divided by the Conversion Price. The Conversion Price is defined as the quotient of the aggregate consideration to be paid to all holders of the Series A Redeemable Convertible Preferred Stock divided by the outstanding number of Series A Redeemable Convertible Preferred Stock, including the shares into which the Bridge Loans convert. Holders of Bridge Loans totaling $2,550,000 elected to convert, immediately prior to the Acquisition Merger. The remaining $100,000 principal amount of the Bridge Loan and accrued and unpaid interest thereon was paid in cash at closing of the Acquisition Merger. In addition, the indebtedness arising under ProSomnus's loan agreement dated August 9, 2019, by and among ProSomnus Sleep Technologies, Inc. and the lenders signatory thereto, in the aggregate principal amount of $6,490,000 (collectively with the Bridge Loan, the "ProSomnus Subordinated Debt"), also converted into shares of ProSomnus Common Stock immediately prior to the Acquisition Merger.

On June 29, 2022, Legacy ProSomnus entered into the Second Amendment and Loan Security Agreement ("Second Amendment") to the subordinated loan and security agreement effective in April 2021. The Second Amendment established a convertible bridge loan advance of up to $2,000,000 to ProSomnus from the lender ("Convertible Bridge Loan Advance"). The interest rate of the Convertible Bridge Loan Advance was 14% and the maturity date was the earlier of the date of the bridge loan conversion event or June 29, 2023. The bridge loan conversion event was the termination of the Merger Agreement or the occurrence of any event that would result in the termination of the Merger Agreement as defined in the Merger Agreement. If the bridge loan conversion had not occurred, and the Convertible Bridge Loan Advance was not repaid in full on the maturity date, the default interest would bear additional 6.0% per annum. Interest was to be paid in arrears at December 29, 2022 and at the maturity date. Prepayment of the Convertible Bridge Loan Advance was permitted in increments of $100,000 at any time, and the prepayment requires the payment of all accrued and unpaid interest as well as a prepayment premium. The prepayment premium was the incremental amount of interest that would have been paid for the term of the convertible bridge advance and had not yet been paid. ProSomnus had received $2,000,000 from the Convertible Bridge Loan Advance as of November 30, 2022.

On December 2, 2022, the Company entered into a Securities Exchange Agreement with holders of the Subordinated Loan and Security agreement and the holders of Convertible Bridge Loan Advance. The Company also executed a payment arrangement with other debt holders on December 6, 2022. The Company agreed to the following key terms and conditions with the holders under these arrangements.

- The Company agreed to exchange an aggregate of $800,000 of existing debt for common stock. An aggregate of 80,000 shares were issued for such debt, along with a bonus of 65,604 shares under this arrangement.

- The Company executed on the Subordinated Securities Purchase Agreement dated August 26, 2022, to issue subordinated notes worth $2,547,879 pursuant to the terms and conditions of such agreement with the holders. The Company issued 42,464 shares of common stock and warrants to purchase 296,456 shares of common stock along with this note.

- The Company paid off the remaining balance of $9,719,135 of the Subordinated Loan and Security Agreement in cash on close of the merger transaction.

All the warrants issued pursuant to the subordinated loan and security agreements were exercised immediately prior to the merger transaction. The Company issued 161,112 shares of Series B redeemable preferred stock to the warrant holders as a cashless exercise. This Series A Redeemable Convertible Preferred Stock was converted to common stock on the close of the merger transaction.

The Company executed on the above terms and conditions on close of the merger transaction. The Company recorded a loss on extinguishment of debt of $2.4 million for the subordinated loan and security agreement and convertible bridge loan advance in accordance with ASC 470-50, *Debt-Modifications and Extinguishments.* There was no outstanding balance on these loans as of December 31, 2022.

Immediately prior to the closing of the Business Combination, the following transactions occurred:

Legacy ProSomnus Series B Convertible Preferred Stock

- 2020 Preferred Series B warrant holders and 2021 Preferred Series B warrant holders exercised their 322,223 warrants, by way of cashless exercise, for 161,112 of Legacy ProSomnus's Series B convertible preferred stock

Legacy ProSomnus Series A Redeemable Convertible Preferred Stock

- The Subordinated Notes automatically converted into the number of Series A Redeemable Convertible Preferred Stock as equal to the repayment amount of the Bridge Loans divided by the Conversion Price. The Company had issued 10,029 shares of Series A Redeemable Convertible Preferred Stock, which got converted into 1,002,869 shares of common stock on the date of the merger transaction based on proceeds of $10.03 million
- Holders of Bridge Loan (Unsecured Subordinated Promissory Notes) elected to convert into Series A Redeemable Preferred Stock. The aggregate amount due, including interest and Bridge Loan Kickers, was $3,052,065, amounting to 3,052 shares of Series A Redeemable Convertible Preferred Stock, this was converted into 305,206 shares of common stock
- Certain Legacy ProSomnus holders received an aggregate of 5,945 shares of Series A Redeemable Convertible Preferred Stock

Legacy ProSomnus Common Stock

- Options to purchase 600,000 shares of Common C stock immediately vested prior to the closing of Business Combination. [An additional 254,507 vested as per their vesting schedule, prior to consummation of the Business Combination]

At the Closing, each issued share of Legacy ProSomnus outstanding immediately prior to the closing, was automatically converted into the right to receive shares of the Company's Common Stock, par value $0.0001 ("Common Stock") at a purchase price of $10.00 as defined in the Merger Agreement.

The company issued an aggregate of 7,208,865 shares of common stock for Legacy ProSomnus Preferred stock as below:

- All 7,288,333 shares of Legacy ProSomnus's outstanding Series B convertible preferred stock and the additional 161,112 Preferred B shares from warrant exercise, totalling 7,449,445 shares; were converted into 2,623,800 shares and 58,000 shares of ProSomnus's common stock, respectively.
- All 45,270 shares of Legacy ProSomnus Series A Redeemable Convertible Preferred Stock were converted into 4,527,065 shares of ProSomnus's common stock.

All 25,420,893 shares of Legacy ProSomnus's Series A Common stock, Series B Common stock and Series C Common stock were converted into 4,084,418 shares of ProSomnus's common stock.

Immediately prior to the Closing of the Business Combination, the Company issued and sold 1,025,000 shares of common stock (the "PIPE – Equity Shares") to the PIPE Investors for gross proceeds of $10,250,000. The PIPE – Equity Shares investors also received an additional 805,133 bonus shares; total issuance to PIPE – Equity investors was 1,830,133 shares of the Company.

Non-redeeming shareholders of Lakeshore retained an aggregate of 480,637 shares, and, the non-redeeming shareholders that entered into agreements with Lakeshore and ProSomnus to not redeem received an aggregate of 340,085 bonus shares; total issuance to these Lakeshare stock holders was 820,722 shares of the Company.

The total of 1,145,218 bonus shares referenced above, issued on close of the Merger transaction by Prosomnus, were sourced from transfer of founder shares, forfeiture of shares by placement agents and new issuances as below:

- 574,035 founder shares were transferred to non-redeeming shareholders that entered into agreements with Lakeshore and ProSomnus to not redeem and new PIPE investors, as a source of bonus shares.
- Underwriters, advisors and convertible notes placement agents totally forfeited $1,640,010 of compensation in exchange of new issuance of 164,010 shares as a source of bonus shares, to be issued to non-redeeming shareholders that entered into agreements with Lakeshore and ProSomnus to not redeem and new PIPE investors.
- The company issued an additional 407,173 of common shares for distribution of bonus shares.

In connection with agreements with certain Underwriters, Advisors and Convertible notes placement agents, the Company issued an aggregate of 716,223 shares of Company's common stock in lieu of cash fees of $7.16 million, net of forfeited compensation, at the close of the Merger transaction.

In connection with the Senior and Subordinated Convertible Notes, the Company issued to the holders of Convertible Notes, warrants to purchase an aggregate of 1,914,907 shares of Company's Common Stock at an exercise price of $11.50 per share, and issued an aggregate of 326,713 shares of Company's Common Stock.

The Merger is accounted for as a reverse recapitalization under accounting principles generally accepted in the United States ("GAAP"). This determination is primarily based on Legacy ProSomnus stockholders comprising a relative majority of the voting power of ProSomnus and having the ability to nominate the members of the Board, Legacy ProSomnus's operations prior to the acquisition comprising the only ongoing operations of ProSomnus, and Legacy ProSomnus's senior management comprising a majority of the senior management of ProSomnus. Under this method of accounting, while the legal acquirer in the Merger Agreement is Lakeshore, for financial accounting and reporting purposes under GAAP, ProSomnus will be the accounting acquirer and the Business Combination will be accounted for as a "reverse recapitalization." A reverse recapitalization does not result in a new basis of accounting, and the financial statements of the combined entity represent the continuation of the financial statements of ProSomnus Inc. in many respects. Accordingly, for accounting purposes, the financial statements of ProSomnus Inc. represent a continuation of the financial statements of ProSomnus Inc. with the Business Combination treated as the equivalent of ProSomnus Inc. issuing stock for the net assets of Lakeshore, accompanied by a recapitalization. The net assets of Lakeshore will be stated at historical cost, with no goodwill or other intangible assets recorded. Operations prior to the Business Combination will be presented as those of ProSomnus Inc.

In connection with the Merger, the Company raised $45.17 million of proceeds including the contribution of $4.92 million of cash held in Lakeshore's trust account from its initial public offering, net of redemptions of Lakeshore's public stockholders of $24.4 million; $10.25 million of gross proceeds in connection with the PIPE Equity financing and approximately $30 million in gross proceeds from the Convertible Notes (Senior and Subordinated Convertible Notes) offering. These proceeds were used to pay transaction expenses and other liabilities of Lakeshore, pay certain transaction expenses of ProSomnus, and pay off approximately $11.53 million in debt of ProSomnus at closing, with the remaining being deposited in ProSomnus' cash account.

NOTE 4 — PROPERTY AND EQUIPMENT

On January 1, 2022 the Company adopted ASC 842 for Leases. Adoption of the new standards resulted in a reclassification of $2,349,591 of assets reported as property, plant and equipment prior to adoption, to right of use assets.

Property and equipment consisted of the following as of December 31:

	2022	2021
Manufacturing equipment	$ 2,516,859	$ 4,420,281
Computers and software	1,608,075	1,547,549
Furniture	27,587	27,587
Leasehold Improvements	441,956	295,471
	4,594,477	6,290,888
Less: accumulated depreciation	(2,190,075)	(2,934,293)
Total Property and equipment, net	$ 2,404,402	$ 3,356,595

Depreciation expense for the years ended December 31, 2022 and 2021 was $424,359 and $827,568 respectively.

NOTE 5 — INVENTORY

Inventory consisted of the following as of December 31:

	2022	2021
Raw Materials	$ 561,726	$ 323,989
Work in progress	78,219	54,780
	$ 639,945	$ 378,769

The company did not have any excess or obsolete inventory reserves as of December 31, 2022 and 2021.

NOTE 6 — ACCRUED EXPENSES

Accrued expenses consisted of the following as of December 31:

	2022	2021
Bonus	$ 832,918	$ 831,601
Wages	218,974	140,962
Vacation	959,004	569,777
Earned discounts	554,642	499,219
Commission settlement	—	274,323
Warranty	269,496	217,244
Other	360,717	264,533
Professional fees	129,169	72,611
Interest	110,239	28,750
401k matching contributions	93,112	100,134
Travel	60,400	—
Credit card fees	60,424	34,424
Marketing expenses	57,000	45,000
	$ 3,706,094	$ 3,078,578

Commission

The Company had an agreement in which it paid commission to an individual for promotional consideration. The agreement required commissions of 15% of sales of the MICRO2 Sleep and Snore Device and the MICRO2 Night Time Orthotic devices.

In December 2017, the Company notified this individual that the individual was in material breach of the contract and in 2018, the Company terminated the contract. In January 2019, the Company settled the dispute and agreed to pay the individual $1,600,000. $400,000 was paid in January 2019 and sixteen (16) quarterly payments of $75,000 are required and commenced in April 2019. The Company recorded the net present value of this obligation in these consolidated financial statements totaling $1,284,825 using the Company's incremental borrowing rate of 15.04% as the originating event for the settlement occurred in 2018. The balance of the remaining settlement totaled $274,323 as of December 31, 2021. There was no outstanding balance on the commission agreement as

of December 31, 2022. The payments under this commission agreement, including interest, totaled $300,000 and were paid in full in 2022.

Invoice Fee Deferral

During 2018 the Company reached an agreement with a vendor allowing the Company to pay less than 100% of the invoiced amounts. Only upon the sale or merger of the Company or upon a public financing would the remaining portion of the invoices become due. As of December 31, 2021, the Company has accrued $291,479, related to the deferred portions. All invoices were paid in full on close of the merger transaction in December 2022

NOTE 7 —LEASES

Prior to the adoption of ASC 842, rent expense on operating leases was recognized on a straight-line basis over the term of the lease. In addition, certain of the Company's operating lease agreements for office space also include rent holidays and scheduled rent escalations during the initial lease term. The Company recorded the rent holidays as deferred rent within other liabilities on the consolidated balance sheets. The Company recognized the deferred rent liability and scheduled rent increase on a straight-line basis into rent expense over the lease term commencing on the date the Company took possession of the leased space.

The Company's previous corporate office lease has a remaining term of approximately twelve months as of December 31, 2022. The Company's operating lease agreement does not contain any material residual value guarantees or material restrictive covenants. The Company recognized right-of-use assets and lease liabilities for such leases in connection with its adoption of ASC 842 as of January 1, 2022. The Company reports operating lease right-of-use assets and the current and non-current portions of its operating lease liabilities on the consolidated balance sheet as of December 31, 2022.

On May 17, 2022, the Company signed a ten-year lease for the Company's corporate headquarters. The lease commenced on December 15, 2022. The monthly payment is approximately $68,000, with stated annual escalation, up to approximately $88,000. The Company received 5 months free rent.

The Company provided a $200,000 security deposit, which is recorded in other assets on the accompanying consolidated balance sheet. The Company's largest investor, at the date of the lease agreement, provided an initial two-year guaranty of $1,700,000 for the benefit of the lessor, followed by a one-year rolling guaranty of the lease performance. The Company can replace the guaranty with a letter of credit for $700,000. The Company recognized a $5.44 million of right of use operating lease liability for this new lease. The Company's new operating lease agreement does not contain any material residual value guarantees or material restrictive covenants.

The Company's finance leases consist of various machinery, equipment, computer-related equipment, or software and have remaining terms from less than one year to five years. The Company reports assets obtained under finance leases in right-of-use assets and the current and non-current portions of its finance leases on the consolidated balance sheet.

During June 2022, two finance leases were extended for an additional ten months. The Company evaluated the terms of the extension and determined that a lease modification occurred. The modification did not meet the requirements to be considered a separate contract. The additional amount of the commitments of approximately $239,000 have been recorded in right-of-use assets and finance lease liabilities on the consolidated balance sheets.

The components of the Company's lease cost, weighted average lease terms and discount rates are presented in the tables below:

	Year ended December 31, 2022
Lease Cost:	
Operating lease cost	$ 324,929
Finance lease cost:	
Amortization of assets obtained under finance leases	$ 772,870
Interest on lease liabilities	288,969
	$ 1,061,839

Lease term and discount rate As of December 31, 2022	Weighted average discount rate:	Weighted average remaining lease term:
Operating leases	10.31 %	9.6 years
Finance leases	11.17 %	3.5 years

	Year ended December 31, 2022
Cash paid for amounts included in the measurement of lease liabilities:	
Operating cash flows from operating leases	$ (159,348)
Operating cash flows from finance leases	772,870
Financing cash flows from finance leases	(1,222,270)
Right-of-use assets obtained in exchange for lease liabilities:	
Acquisition of ROU assets through operating leases	$ 5,435,661
Acquisition of property and equipment through finance leases	2,233,834
Addition of ROU assets from finance lease modification	239,000
	$ 2,472,834

Right-of-use assets consisted of the following as of December 31, 2022:

	Total
Manufacturing equipment	$ 4,673,618
Computers and software	700,234
Leasehold Improvements	218,244
Total	5,592,095
Less: accumulated amortization	(1,941,644)
Right-of-use assets for finance leases	3,650,451
Right-of-use assets for operating leases	5,632,771
Total right-of-use assets	$ 9,283,222

At December 31, 2022, the following table presents maturities of the Company's finance lease liabilities:

Years ending	Total
2023	$ 1,275,119
2024	863,280
2025	785,386
2026	597,933
2027	190,283
Thereafter	—
Total minimum lease payments	3,712,001
Less amount representing interest	(622,004)
Present value of minimum lease payments	3,089,997
Less current portion	(1,008,587)
Finance lease obligations, less current portion	$ 2,081,410

At December 31, 2022, the following table presents maturities of the Company's operating lease liabilities:

Years ending December 31,	Total
2023	$ 794,619
2024	836,280
2025	861,372
2026	887,208
2027	913,824
Thereafter	4,997,184
Total minimum lease payments	9,290,487
Less: amount representing interest	(3,549,882)
Present value of minimum lease payments	5,740,605
Less: current portion	(215,043)
Operating lease liabilities, less current portion	$ 5,525,562

Total rent expense for the years ended December 31, 2022 and 2021 ended was $325,683 and $250,495, respectively.

NOTE 8 — DEBT

Equipment Financing Obligation

Two equipment financing arrangements entered in to during 2018 and 2020 were guaranteed by the Company's primary stockholder (at that period) until November 2022. The balance of these notes was $244,618 and $299,950 at December 31, 2022 and 2021, respectively. Interest expense on the notes totaled $30,497 and $36,167 for the years ended December 31, 2022 and 2021, respectively.

At December 31, 2022, the Company's future principal maturities under the equipment financing obligation are summarized as follows:

Years ending	Total
2023	$ 58,973
2024	56,995
2025	63,698
2026	64,952
2027	—
Total principal maturities	244,618
Less: current portion	(58,973)
Equipment financing obligation, net of current portion	$ 185,645

Line of Credit

The Company entered into a Loan and Security Agreement in 2018 with a financial institution. The balance on the line of credit was paid off at the close of merger transaction, there was no credit available as of year ended December 31, 2022. The balance of the line of credit was $587,816 at December 31, 2021. Interest expense on the line of credit totaled $247,334 and $135,581 for the years ended December 31, 2022 and 2021, respectively.

Subordinated Notes

Prior to January 2020, the Company received advances under unsecured subordinated promissory note agreements for gross proceeds of $2,208,299, net of issuance costs of $76,701. The Company received advances under unsecured subordinated promissory note agreements for total proceeds of $375,000 and $2,765,000 during the years ended December 31, 2022 and 2021, respectively. No issuance costs were incurred in 2022 and 2021.

These advances are subordinate to the line of credit and Subordinated Loan and Security Agreement. $250,000 and $1,440,000 of these advances were made by the Company's stockholders, directors, and employees as of December 31, 2022 and 2021, respectively. $50,000 and $1,330,000 of these advances were made by the Company's customers as of December 31, 2022, and 2021, respectively. Amortization of the issuance costs totaled $18,184 and $18,273 for the years ended December 31, 2022 and 2021, respectively.

On May 4, 2022, the Company's Board of Directors amended the terms of the unsecured subordinated promissory note agreements to provide for the automatic conversion of the outstanding loan amounts (including principal, interest and prepayment and change of control premiums, as well as a 5% equity kicker to incentivize lenders to agree to the amendment) into shares of Series A Redeemable Convertible Preferred Stock of the Company immediately prior to the closing of the merger transaction so that such lenders receive shares of common stock at the closing.

Noteholders had the option to elect between two forms of the amendments:

1. Interest is received as a cash payment ("Cash Notes") and paid on a quarterly basis every January 1, April 1, July 1 and October 1. The annual interest rate on these notes is 15% per annum based on a 360-day year. $750,000 of the proceeds related to the Cash Notes. Interest expense totaled $181,067 (including kickers at closing) and $114,062 for the years ended December 31, 2022 and 2021, respectively, for the Cash Notes.

2. Interest is accrued and added to the principal balance ("PIK Notes") at the commencement of each new calendar year (January 1). The annual interest rate on these notes is 20% per annum based on a 360-day year. $5,440,000 of the proceeds related to the PIK Notes as of December 31, 2021. Interest expense totaled $2,251,260 (including kickers at closing) and $710,443 for the years ended December 31, 2022 and 2021, respectively, for the PIK Notes.

Both the Cash and PIK notes have a prepayment penalty that is calculated on the principal and all accrued but unpaid interest at the following rates:

Less than one (1) year from the funding date	3 %
One (1) year to less than two (2) years from the funding date	2 %
Two (2) years to less than three (3) years from the funding date	1 %
A change in control event	5 %

All note holders elected to convert the bridge loan into Series A Redeemable Convertible Preferred Stock of the Company immediately prior to the closing of the proposed merger. This Series A Redeemable Convertible Preferred Stock was converted to common stock of ProSomnus on close of the merger transaction. The company had issued 1,002,869 shares of Series A Redeemable Convertible Preferred Stock, which got converted into 10,029 shares of common stock on the date of the merger transaction.

Bridge Loan (Unsecured Subordinated Promissory Notes)

During February and March 2022, the Company received proceeds of $3,000,000 from unsecured subordinated promissory notes (the "Bridge Loans"). Interest accrues at 15% per annum, and all accrued but unpaid interest is applied and added quarterly to the principal balance (the "Base Amount"). The maturity date is two years from the date of funding or upon a change in control of the Company. The interest is increased to an amount equal to 103% of the Base Amount if the Bridge Loans are repaid upon the closing of a change of control in the Company. The Bridge Loans are subordinate to the line of credit and Subordinated Loan and Security Agreement.

During March 2022, $500,000 of the Bridge Loans were repaid. The primary stockholder of the Company was the borrower on this Bridge Loan, and a representative of this primary stockholder is a member of the Company's Board of Directors.

During April 2022, the Company received proceeds of $150,000 from additional Bridge Loans.

On May 4, 2022, the Company's Board of Directors approved a resolution to amend the terms of the Bridge Loans to grant an additional 5% of the Base Amount (the "Bridge Loan Kicker") to each bridge lender who exercises its option to convert its bridge loan, which Bridge Loan Kicker will be payable in shares of Series A Redeemable Convertible Preferred Stock so that such exercising lenders will receive shares of common stock issuable at the closing thereof.

During May and June 2022, the Company and certain holders of the Bridge Loans executed a conversion addendum. Upon notice of the Business Combination Agreement, the holders of the Bridge Loans had up to 10 days to elect to convert into Series A Redeemable Convertible Preferred Stock. Immediately prior to the closing of the Business Combination, the Bridge Loans will automatically convert into the number of Series A Redeemable Convertible Preferred Stock as equal to the repayment amount of the Bridge Loans divided by the Conversion Price. The Conversion Price is defined as the quotient of the aggregate consideration to be paid to all holders of the Series A Redeemable Convertible Preferred Stock divided by the outstanding number of Series A Redeemable Convertible Preferred Stock, including the shares into which the Bridge Loans convert. Holders of Bridge Loans totaling $2,550,000 who elected to convert into Series A redeemable convertible preferred stock, received common stock of ProSomnus on the close of the merger transaction. As of date of conversion, the aggegrate amount due, including interest and Bridge Loan Kickers, was $3,052,065, amounting to 305,206 shares of Series A Redeemable Convertible Preferred Stock, this was converted into 3,052 shares of common stock.

Subordinated Loan and Security Agreement

In January 2020, the Company entered into a loan and security agreement with a lender and borrowed $3,800,000 ("SMC Loans"). The loan is subordinate to the line of credit. The loan was secured by substantially all assets of the Company, and contained certain financial and non-financial covenants and had a four-year term. The loan was repayable monthly starting February 2021 at an amount equal to 4% of net revenues of the Company until the Company had paid an amount equal to the return cap of $9,500,000. The return cap was subject to a reduction of 30% if fully repaid within 12 months, 22% if fully repaid within 24 months and 11.85% if fully repaid within 36 months.

In April 2021, the Company entered into a second loan and security agreement with the same lender and borrowed $2,000,000 ("SMC Loans"). The loan is subordinate to the line of credit. The loan is secured by substantially all assets of the Company, contains certain financial and non-financial covenants and has a three-year term. The loan is repayable monthly starting February 2021 at an amount initially equal to 1.0526% of net revenues of the Company and increasing to 2.105% in the second year of the agreement, until the Company has paid an amount equal to the return cap of $3,902,800. The return cap is subject to a reduction of 22% if fully repaid within 12 months and 11.85% if fully repaid within 24 months. During the year ended December 31, 2022 and 2021, the Company made revenue share payments totaling $1,580,019 and $602,637, respectively.

The effective interest rates on the subordinated loan and security agreement ranged from 25.8% - 27.2% and 25.8% - 26.2% for the years ended December 31, 2022 and 2021, respectively. The effective interest rate is adjusted to reflect the actual cash flows paid to date and the revised estimate of future cash flows for revenue share payments. The Company records the impact of the change in the cash flows in the current and future periods.

The outstanding balance of the subordinated loan and security agreement was paid off as of December 31, 2022. The outstanding balance of the subordinated loan and security agreement for principal plus accrued interest was $6,589,563 as of December 31, 2021 includes the principal amount of $4,876,496 and accrued interest of $2,681,560. The prior period presentation of this debt was updated to conform to the current period presentation.

As of December 31, 2021, the Company had a compensating balance arrangement under the loan and security agreement which required a minimum cash deposit to be maintained in the amount of $500,000.

Bridge Loan (Secured subordinated loan)

On June 29, 2022, the Company entered into the Second Amendment and Loan Security Agreement ("Second Amendment") to the subordinated loan and security agreement effective in April 2021. The Second Amendment established a convertible bridge loan advance of up to $2,000,000 to the Company from the lender ("Convertible Bridge Loan Advance"). The interest rate of the Convertible Bridge Loan Advance is 14% and the maturity date is the earlier of the date of the bridge loan conversion event or June 29, 2023. The bridge loan conversion event is the termination of the Merger Agreement (see Note 3) or the occurrence of any event that would result in the termination of the Merger Agreement as

defined in the Merger Agreement. If the bridge loan conversion has not occurred, and the Convertible Bridge Loan Advance is not repaid in full on the maturity date, the default interest will bear additional 6.0% per annum. Interest is paid in arrears at December 29, 2022 and at the maturity date. Prepayment of the Convertible Bridge Loan Advance is permitted in increments of $100,000 at any time, and the prepayment requires the payment of all accrued and unpaid interest as well as a prepayment premium. The prepayment premium is the incremental amount of interest that would have been paid for the term of the convertible bridge advance, this amount was paid in full on close of the merger transaction. Interest expense from the Bridge Loans was $101,548 for the year ended December 31, 2022.

The Company recorded the amendment of the subordinated loan and security agreement in accordance with ASC 470-50, *Debt-Modifications and Extinguishments*, and recorded a loss on extinguishment of debt of $192,731 in the consolidated statements of operations.

Upon the occurrence of a bridge loan conversion event, the bridge loan advance balance is calculated at the amount of the principal outstanding plus a 14% premium and is considered to have been outstanding since the second amendment date of June 29, 2022.

Extinguishment of Subordinated Loan and Security Agreement and Bridge Loan (Secured subordinated loan)

On December 2, 2022, the Company entered into a Securities Exchange Agreement with holders of the Subordinated Loan and Security agreement and the holders of Convertible Bridge Loan Advance. The Company also executed a payment arrangement with other debt holders on December 6, 2022. The Company agreed to the following key terms and conditions with the holders under these arrangements.

- The Company agreed to exchange an aggregate of $800,000 of existing debt for common stock. An aggregate of 80,000 shares were issued for such debt, along with a bonus of 65,604 shares under this arrangement.

- The Company executed on the Subordinated Securities Purchase Agreement dated August 26, 2022, to issue subordinated notes worth $2,547,879 pursuant to the terms and conditions of such agreement with the holders. The company issued 42,464 shares of common stock and warrants to purchase 296,456 shares of common stock along with this note.

- The Company paid off the remaining balance of $9,719,135 of the Subordinated Loan and Security Agreement in cash on close of the merger transaction.

All the warrants issued pursuant to the subordinated loan and security agreements were exercised immediately prior to the merger transaction. The Company issued 161,112 shares of Series B redeemable preferred stock to the warrant holders as a cashless exercise. This Series A Redeemable Convertible Preferred Stock was converted to common stock on the close of the merger transaction.

The Company executed on the above terms and conditions on close of the merger transaction. The Company recorded in the consolidated statement of operations, a loss of debt extinguishment of $2,405,111 for the subordinated loan and security agreement and

convertible bridge loan advance in accordance with ASC 470-50, *Debt-Modifications and Extinguishments.* There was no outstanding balance on these loans as of December 31, 2022.

Paycheck Protection Program Loan

The Paycheck Protection Program ("PPP") was established under the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") and is administered by the U.S. Small Business Administration ("SBA"). On May 6, 2020, the Company entered into a promissory note evidencing an unsecured loan in the aggregate amount of $1,278,150 made to the Company under the PPP ("PPP Loan 1"). On February 2, 2021, the Company entered into a second unsecured promissory note in the aggregate amount of $1,003,112 made to the Company under the PPP ("PPP Loan 2").

The PPP Loan to the Company was being made through Home Loan Investment Bank FSB. The interest rate on the PPP Loan was 1% and the term was two years. In accordance with the updated Small Business guidance, the PPP Loan was modified so that, beginning ten months from the date of the PPP Loan, the Company was required to make monthly payments of principal and interest. The promissory note evidencing the PPP Loan contained customary events of default relating to, among other things, payment defaults or breaching the terms of the PPP Loan documents. The occurrence of an event of default may result in the repayment of all amounts outstanding, collection of all amounts owing from the Company, or filing suit and obtaining judgment against the Company.

On June 16, 2021, the Company submitted an application for forgiveness of $1,278,150 due on the PPP Loan 1. On June 30, 2021, the Company was notified that the principal balance of the PPP Loan 1 and accrued interest were fully forgiven. On September 16, 2021, the Company submitted an application for forgiveness of $1,003,112 due on the PPP Loan 2. On September 28, 2021, the Company was notified that the principal balance of the PPP Loan 2 and accrued interest were fully forgiven.

As a result, the Company recorded a gain in the amount of $2,281,262 to other income in the consolidated statement of operations during the year ended December 31, 2021. As of December 31, 2022 and 2021, the Company had an outstanding balance of $0 and $0, respectively, under the PPP Loans.

Convertible Debt Agreements

On August 26, 2022, Lakeshore and ProSomnus entered into definitive agreements with certain investors pursuant to which convertible promissory notes with an aggregate principal funding equal to thirty million dollars ($30,000,000) was to be issued to such investors in a private placement to be consummated immediately prior to the consummation of the Business Combination.

Senior Convertible Notes

On December 6, 2022, the Company entered into that certain Senior Indenture by and between ProSomnus, Inc., ProSomnus Holdings, ProSomnus Sleep Technologies, and Wilmington Trust, National Association, as Trustee and Collateral Agent, and Senior Secured Convertible Notes Due December 6, 2025 ("Senior Convertible Notes"), with an aggregate principal amount of $16.96 million, pursuant to the previously disclosed Senior Securities Purchase Agreement, dated August 26, 2022. In connection with the closing of this Convertible Debt offering, the Company issued 36,469 shares of common stock and 169,597 warrants ("Convertible Notes warrants") to purchase common stock. These warrants entitle the Holders to purchase shares of common stock of the Company, subject to adjustment, at a purchase price per share of $11.50. The debt has an interest rate of 9% per annum with a term of 3 years.

Subordinated Convertible Notes

On December 6, 2022, the Company entered into that certain Subordinated Indenture by and between ProSomnus, Inc., ProSomnus Holdings, ProSomnus Sleep Technologies, and Wilmington Trust, National Association, as Trustee and Collateral Agent, and Subordinated Secured Convertible Notes Due April 6, 2026 ("Subordinated Convertible Notes"), with an aggregate principal amount of $17.45 million, pursuant to the previously disclosed Subordinated Securities Purchase Agreement, dated August 26, 2022. In connection with the closing of this Convertible Debt offering, the Company issued 290,244 shares of common stock and 1,745,310 warrants ("Convertible Notes warrants") to purchase common stock to certain Convertible Debt holders. The debt has an interest rate of Prime Rate plus an additional 9% per annum with a term of 3 years.

The Convertible Notes included the following embedded features:

Embedded Feature	Nature	Description
(1) Optional redemption – Election of Company	Redemption feature (embedded call option)	At any time after the later of (i) the eighteen-month anniversary of the initial issue date and (ii) the date that the Senior Debt is no longer outstanding, if the daily volume weighted-average price of the Company's common stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days exceeds $18.00, the Company may redeem a portion of or all of the principal amount (including accrued and unpaid interest) + any liquidated damages and any other amounts due in respect of the Notes redeemable in cash.
(2) Mandatory redemption – Events of Default	Redemption feature (embedded contingent call option)	The Company is required to prepay all of the outstanding principal balance and accrued and unpaid interest upon bankruptcy-related events of default.
(3) Lenders' Optional redemption – Events of Default	Redemption feature (embedded contingent call option)	Holders of at least 25% aggregate principal amount of the Notes can require the Company to pay all of the outstanding principal balance and accrued and unpaid interest upon any event of default that is not bankruptcy related.
(4) Lender's Optional Conversion	Conversion feature	At each Lenders' option, subject to specific conditions, it may convert all or any portion of its Notes at an initial conversion rate of 86.95652173913043, which is reduced (and only reduced) at various dates and subject to certain adjustments to the conversion rate in the case of specified events. If a note is converted, the Company will adjust the conversion rate to account for any accrued and unpaid interest on such note plus any Make-Whole Amount related to such note.
(5) Lenders' Optional Conversion Upon Merger Event	Other feature	Upon a merger event, Note holders of each $1,000 principal amount of Notes are entitled to convert such notes plus accrued interest, plus the Make-Whole Amount related to the in kind and amount of reference property that a holder of a number of shares of common stock equal to the conversion rate in effect immediately prior to such event would have owned or been entitled to receive upon such event
(6) Additional interest rate upon certain non-credit related events	Other feature	Upon an event of default, additional interest will be incurred. Additional interest will also be incurred if the Notes are not freely tradeable
(7) Ability to pay interest in kind (PIK Interest)*	Other feature	The Company has the election to pay interest in cash or in-kind.

**The PIK interest feature was only present in the Subordinated Convertible Note, and not available in the Senior Convertible Notes*

The Company assessed the embedded features within these Convertible Note and determined the following:

- the Optional Redemption feature (1) , the Mandatory redemption feature (2) and the Lender's Optional redemption feature (3) met the definition of a derivative and were not clearly and closely related to the host contract and required separate accounting. Further, the redemption features are settled in cash and would therefore not meet the indexed to equity and equity classification scope exception. Thus, these redemption features were concluded to be embedded derivatives that should be bifurcated from the loan and accounted for separately at fair value on a recurring basis through the income statement.
- The Lender's Optional Conversion feature (4) and the Lender's Optional Conversion Upon Merger (5) event features also met the definition of a derivative and were not clearly and closely related to the host contract and required separate accounting. The economic characteristics of the Lender's Optional Conversion feature (4) and the Make Whole premium on Lenders' Optional Conversion Upon Merger Event (5) were based on fair value of the underlying shares. The settlement amount of the interest make-whole is not indexed to the issuer's equity but it is based on stated interest cash flows. The Lenders Optional Conversion Upon Merger event feature is contingent on merger event, this exercise contingency is allowable as it is not based on market or an observable index. The company noted that features (4) and (5) did not meet the indexed to equity and equity classification scope exception. Thus, these conversion features were concluded to be embedded derivatives that should be bifurcated from the loan and accounted for separately at fair value on a recurring basis through the consolidated statement of operations.
- The additional interest rate upon certain non-credit related events (6) are triggered based on timely filing of financial information and the tradability of the Notes, these are not related to the economic characteristics of debt. Therefore, this feature

is not clearly and closely related to the debt host. The additional interest payment is settled in cash and hence did not meet the derivative scope exception. However, since the probability of the Convertibles Notes being freely tradeable or Company's failure to timely file is estimated to be less than 5%, the company concluded that the fair value of this feature is not material. Thus, even though this additional interest feature was concluded to be embedded derivatives, it will not be fair valued separately.

- The ability to pay PIK interest feature is clearly and closely related to the debt, and will not be evaluated separately as a derivative feature.

The Company determined the Notes contained multiple embedded derivatives that are required to be bifurcated, two of which are conversion features. As per ASC 815, if there is a conversion feature that is required to be bifurcated, the cash conversion feature and beneficial conversion feature guidance is not applicable to such conversion feature and the fair value election is allowable provided the debt was not issued at a substantial premium. As the proceeds received at issuance from these Convertible Notes do not exceed the principal amount that will be paid at maturing, there is no substantial premium.

Further, ASC 815-15-25 provides that if an entity has a hybrid financial instrument that would require bifurcation of embedded derivatives under ASC 815, the entity may irrevocably elect to initially and subsequently measure a hybrid financial instrument in its entirety at fair value with changes in fair value recognized in earnings. The Company elected to measure the Senior and Subordinated Convertible Notes in their entirety at fair value with changes in fair value recognized as non-operating gain or loss in the consolidated statement of operations at each balance sheet date in accordance with ASC 815-15-25.

The estimated fair value of the convertible note payable was determined using a Monte Carlo Simulation method. We simulated the stock price using a Geometric Brownian Motion until maturity. For each simulation path we calculated the convertible bond value at maturity and then discount that back to the valuation date. Finally, the value of the convertible bond is determined by averaging the discounted cash flows of all the simulated paths. The following assumptions were used as of issuance date of December 6, 2022 and as of December 31, 2022.

	Monte Carlo Simulation Assumptions			
Convertible Notes Issuance - December 6, 2022	**Asset Price**	**Risky Yield**	**Expected Volatility**	**Risk-Free Interest Rate**
Senior Convertible Notes	$ 8.69	30.80 %	40 %	4.07 %
Subordinated Convertible Notes	8.69	40.20 %	40 %	4.01 %

As of December 31, 2022	**Asset Price**	**Risky Yield**	**Expected Volatility**	**Risk-Free Interest Rate**
Senior Convertible Notes	$ 5.56	31.80 %	45 %	4.23 %
Subordinated Convertible Notes	5.56	41.20 %	45 %	4.19 %

The following is a summary of Fair value of Convertible Notes on issuance and as of December 31, 2022.

Convertible Notes	**Convertible Notes as of December 31, 2021**	**Fair value of Convertible Notes on Issuance**	**Change in fair value of Convertible Notes**	**Fair Value of Convertible Notes December 31, 2022**
Senior Convertible Notes	$ -	$ 14,536,000	$ (885,000)	$ 13,651,000
Subordinated Convertible Notes	-	10,223,000	(69,000)	10,154,000

The change in fair value was offset by $311,919 of interest accrued on Senior and Subordinated debt and $83,000 of issuance costs. An additional net expense of $5,845 was recorded to change in fair value on account of issuance of warrants and an issue discount on Senior and Subordinated debt, that was offset by a gain in fair value on date of issuance of the Senior and Subordinated debt.

NOTE 9 – COMMON STOCK WARRANTS

As of December 31, 2022, the Company has 6,512,087 warrants outstanding. The exercise price for the warrants is $11.50 per share. An aggregate of 1,914,907 warrants were issued by the Company with issuance of Senior and Subordinated Convertible Notes (See

Footnote 8 – Debt). Additionally, 4,597,180 warrants were issued to holders of Lakeshare founder shares, and private and public warrant holders, as a result of the Business Combination, detailed as below:

- At the Closing of the Business Combination, 196,256 Private Placement Warrants held by the Sponsor, each exercisable for one ordinary share of Lakeshore at $11.50 per share, automatically converted into warrants to purchase one share of ProSomnus common stock at $11.50 per share. (Private Warrants)

- At the Closing of the Business Combination, 4,100,239 Public Warrants of Lakeshore, originally issued in the initial public offering of Lakeshore, were converted into 4,100,239 common stock warrants of ProSomnus common stock at $11.50 per share. (Public Warrants)

- Pursuant to Amended and Restated Purchaser Support Agreement dated November 28, 2022 between the Company and Lakeshore, at the closing of the Business Combination, the Company issued an additional 300,685 warrants of the Company's common stock to founders of Lakeshore at substantively identical terms as the Private Placement warrants and the Public warrants. (Additional Private Warrants)

As of December 31, 2021, the Company had an aggregate of 322,223 warrants outstanding. These warrants were issued in connection with the loan and security agreement by the Company. (See Footnote 8 – Debt).

The following is a summary of the Company's warrant activity for the year ended December 31, 2022.

Warrant Issuance	Issuance Period	Outstanding December 31, 2021	Granted	Exercised	Cancelled	Oustanding December 31, 2022	Expiration
Convertible Notes Warrants - Senior Debt	Dec-22	—	169,597	—	—	169,597	Dec-27
Convertible Notes Warrants – Subordinated Debt	Dec-22	—	1,745,310	—	—	1,745,310	Dec-27
Private Warrants	Dec-22	—	196,256	—	—	196,256	Dec-27
Public Warrants	Dec-22	—	4,100,239	—	—	4,100,239	Dec-27
Additional Private Warrants	Dec-22	—	300,685	—	—	300,685	Dec-27
2021 preferred Series B warrants	Jan-20	111,111	—	(111,111)	—	—	Jan-30
2020 preferred Series B warrants	Apr-21	211,112	—	(211,112)	—	—	Apr-31
		322,223	6,512,087	(322,223)	—	6,512,087	

Warrants classified as Liabilities

Warrants in connection with the Loan and Security Agreement

In connection with the Loan and Security Agreement, the Company issued a warrant to the lender for the purchase of 211,112 shares of Series B redeemable convertible preferred stock, with an exercise price of $1.80 per share (subject to a valuation cap of $150,000,000 in the event of a liquidation) and a term of ten years ("2020 preferred Series B warrants"). The fair value of the warrant at issuance was $228,000. The fair value of such warrant was estimated using the Black-Scholes Model based on the following weighted average assumptions: redeemable convertible preferred share price on date of grant $1.80, expected dividend yield 0%, expected volatility 26%, risk-free interest rate 0.93% and expected life of ten years.

In connection with the second loan and security agreement, the Company issued warrants to the lender for the purchase of 111,111 shares of Series B redeemable convertible preferred stock, with an exercise price of $1.80 per share (subject to a valuation cap of $150,000,000 in the event of a liquidation) and a term of ten years ("2021 preferred Series B warrants"). The fair value of the warrant at issuance was $143,333. The fair value of such warrant was estimated using the Black-Scholes Model based on the following weighted average assumptions: redeemable convertible preferred share price on date of grant $1.80, expected dividend yield 0%, expected volatility 27%, risk-free interest rate 1.73% and expected life of ten years.

The fair value of warrants was recorded within noncurrent liabilities as a debt discount and a warrant liability, with changes in fair value recognized in the consolidated statements of operations. During the years ended December 31, 2022 and 2021, the Company recognized interest expense of $47,046 and $89,750, respectively, upon amortization of the debt discounts. There was no balance of the debt discount as of December 31, 2022. The debt discount at December 31, 2021 was $242,277.

All of the warrants issued pursuant to these loan and security agreements were exercised immediately prior to the merger transaction. The Company issued 161,112 shares of Series B redeemable preferred stock to the warrant holders in a cashless exercise. The Series A Redeemable Convertible Preferred Stock was converted to common stock of ProSomnus on close of the merger transaction. There were no outstanding 2021 preferred Series B warrants and 2020 preferred Series B warrants in connection with the Loan and Security Agreement as of December 31, 2022.

Convertible Notes Warrants

In connection with closing of the Senior Convertible notes offering, the Company issued 169,597 warrants to purchase common stock. These warrants entitle the holders to purchase shares of common stock of the Company, subject to adjustment, at a purchase price per share of $11.50 and have a term of five years. Further, in connection with the closing of Subordinated Convertible notes offering, 1,745,310 warrants to purchase common stock to the Convertible Notes holders. These warrants entitle the Holders to purchase shares of common stock of the Company, subject to adjustment, at a purchase price per share of $11.50 and have a term of five years.

The Convertible Notes Warrants were classified as a derivative liability because the settlement provisions for the warrants contain adjustments to the settlement amount that do not meet the fixed-for-fixed test, thus these did not qualify as being indexed to the Company's own common stock and are measured at fair value on a recurring basis.

The aggregate fair value of these warrants at issuance was $5,246,845.

Estimated Fair Value of Outstanding Warrants Classified as Liabilities

The estimated fair value of outstanding warrants classified as liabilities is determined at each consolidated balance sheet date. Any decrease or increase in the estimated fair value of the warrant liability since the most recent consolidated balance sheet date is recorded in the consolidated statements of operations as a change in fair value of warrant liability.

The fair value of the outstanding warrants accounted for as liabilities as of December 6, 2022, December 31, 2022 and December 31, 2021 are calculated using the Black-Scholes option pricing model with the following assumptions:

			Black-Scholes Fair Value Assumptions			
As of Issuance date - December 6, 2022	**Exercise Price**	**Asset Price**	**Dividend Yield**	**Expected Volatility**	**Risk-Free Interest Rate**	**Expected Life**
Convertible Notes Warrants - Senior Debt	$ 11.50	$ 8.69	0 %	40 %	3.70 %	5.00 years
Convertible Notes Warrants - Subordinated Debt	11.50	8.69	0 %	40 %	3.70 %	5.00 years

As of December 31, 2022	**Exercise Price**	**Asset Price**	**Dividend Yield**	**Expected Volatility**	**Risk-Free Interest Rate**	**Expected Life**
Convertible Notes Warrants - Senior Debt	$ 11.50	$ 5.56	0 %	40 %	4.00 %	4.93 years
Convertible Notes Warrants - Subordinated Debt	11.50	5.56	0 %	40 %	4.00 %	4.93 years

			Black-Scholes Fair Value Assumptions			
As of December 31, 2021	**Exercise Price**	**Asset Price**	**Dividend Yield**	**Expected Volatility**	**Risk-Free Interest Rate**	**Expected Life**
2021 preferred Series B warrants	$ 1.80	$ 2.89	0 %	20 %	1.52 %	9.26 years
2020 preferred Series B warrants	1.80	2.89	0 %	20 %	1.52 %	8.10 years

Warrants Classified as Equity

Private warrants, Public warrants and Additional Private warrants

Certain warrants are classified as equity instruments since they do not meet the characteristics of a liability or a derivative and are recorded at fair value on the date of issuance using the Black-Scholes option pricing model. The fair value as determined at the issuance date is recorded as an issuance cost of the related stock.

At close of Business Combination, the Company issued an aggregate of 4,597,180 warrants to holders of Lakeshare founder shares, and to the private and public warrant holders, as a result of the Reincorporation Merger and the Business Combination agreements. The Public and Private warrants were issued in June 2021, pursuant to the initial public offering of Lakeshore; each warrant was exercisable for one ordinary share of Lakeshore at $11.50 per share. These automatically converted into warrants to purchase one share of ProSomnus common stock at $11.50 per share on consummation of the Business Combination with an expiry of 5 years, redeemable at $18.00 per share redemption trigger price.

ASC 815-10-15-74(a) provides a scope exception from Derivative Acccounting if the financial instruments meet the following conditions:

Contracts issued or held by that reporting entity that are both:

1. *Indexed to its own stock (see Section 815-40-15)*
2. *Classified in stockholders' equity in its statement of financial position (see Section 815-40-25).*

The Company has concluded that the Warrants meet the derivative scope exception in 815-10-15-74(a) as the Warrants are both indexed to the Company's own stock, and meet the equity classification conditions within ASC 815-40-25. These warrants have been classified as Equity and recorded to additional paid in capital at the grant date fair value on date of issuance. The aggregate fair value of these warrants at issuance was $666,600. The fair value of such warrant was estimated using observable market inputs, the closing price of Lakeshore public warrants was $0.145 as of December 6, 2022.

The changes in fair value of the outstanding warrants classified as liabilities for the year ended December 31, 2022 and 2021 were as follows:

Warrant Issuance	Warrant liability, December 31, 2021	Fair value of warrants granted	Fair value of warrants exercised	Change in fair value of warrants	Warrant liability, December 31, 2022
Convertible Notes Warrants - Senior Debt	$ -	$ 464,696	$ -	$ (288,315)	$ 176,381
Convertible Notes Warrants - Subordinated Debt	-	4,782,149	-	(2,967,027)	1,815,122
2020 preferred Series B warrants and 2021 preferred Series B warrants	562,244	-	(580,000)	17,756	-

Warrant Issuance	Warrant liability, December 31, 2020	Fair value of warrants granted	Fair value of warrants exercised	Change in fair value of warrants	Warrant liability, December 31, 2021
2020 preferred Series B warrants and 2021 preferred Series B warrants	$ 228,000	$ 143,333	$ -	$ 190,911	$ 562,244

There were 4,597,180 equity classified warrants granted during the year ended December 31, 2022.

NOTE 10 – FAIR VALUE

At December 31, 2022 and 2021, the warrants related to the Senior and Subordinated convertible notes, warrant liability and the Earnout liability are classified within Level 3 of the valuation hierarchy. (See Footnote 8 – Debt for change in fair value of Senior and Subordinated convertible notes and Footnote 7 – Common Stock warrants for change in fair value of warrants).

The following tables provide a summary of the financial instruments that are measured at fair value on a recurring basis as of December 31, 2022 and 2021:

		December 31, 2022		
	Fair Value	Level 1	Level 2	Level 3
Senior Convertible Notes	$ 13,651,000	$ —	$ —	$ 13,651,000
Subordinated Convertible Notes	10,355,681	—	—	10,355,681
Earn-out liability	12,810,000	—	—	12,810,000
Warrant liability	1,991,503	—	—	1,991,503

		December 31, 2021		
	Fair Value	Level 1	Level 2	Level 3
Warrant liability	$ 562,244	$ —	$ —	$ 562,244

A financial instrument's level within the fair value hierarchy is based on the lowest level of input that is significant to the fair value measurement.

NOTE 11 – COMMON STOCK

The Company was authorized to issue up to 101,000,000 shares of all classes of stock at a par value of $0.0001 per share as of December 31, 2022. The Company was authorized to issue 36,038,535 shares of all classes of common stock at a par value of $0.0001 per share as of December 31, 2021.

At December 31, 2022 the common stock consisted of the following:

	Shares Authorized	Shares issued and outstanding	Liquidation Amount
Common Stock*	100,000,000	16,041,464	$ —
Preferred Stock	1,000,000	—	-
Total	101,000,000	16,041,464	$ —

*excludes shares issued as an 'Escrow Reserve'

At December 31, 2021 the common stock consisted of the following:

	Shares Authorized	Shares issued and outstanding	Liquidation Amount
Series A	30,415,100	20,179,645	$ 5,355,678
Series B	1,675,600	1,673,092	977,755
Series C	3,947,835	2,713,649 *	1,192,377
Total	36,038,535	24,566,386	$ 7,525,810

*Represents fully vested Series C Shares

The Company has reserved shares of Common Stock for the following as of December 31, 2022:

2022 Equity Incentive Plan reserve	2,411,283
Reserve for Earn-out shares	3,000,000
Reserve for exercise of Public Warrants	4,100,250
Reserve for exercise of Private Warrants	496,941
Total	10,008,474

Immediately following the Business Combination there were 16,041,464 shares of Common stock with a par value of $0.0001 issued and outstanding and 6,512,087 shares of Common stock warrants. The Company also issued 339,000 shares as an "Escrow reserve" for Merger Consideration Adjustment, if any, pursuant to the Merger Agreement. The company evaluated the merger consideration on March 5, 2023, and determined there were no shares issued on account of the Merger Consideration adjustment.

NOTE 12 — REDEEMABLE CONVERTIBLE PREFERRED STOCK

During May and December 2022, the Board approved the issuance of an aggregate of 5,945 shares, respectively, of Series A Redeemable Convertible Preferred Stock to certain employees of the Company for no cash consideration but in exchange for their services as members of the Company's management. The Company recorded stock compensation expense of $2,145,000 related to these awards. The Company calculated the grant date fair value of the awards using the valuations prepared by an independent third-party valuation firm, which were approved by the Board or the issuance price of $10 per share at the Business Combination date. (See Note 14 – Stock Compensation).

In connection with the Business Combination, the ProSomnus common and redeemable convertible preferred stockholders received 11,300,000 shares of Surviving Pubco common stock as Merger Consideration. As of December 31, 2022, there were no outstanding Series A and B Redeemable Convertible Preferred Stock of the Company. These original holders of such common and redeemable preferred stock also received a contingent right to receive Earn-Out Shares as set forth in the Merger Agreement. See Footnote 13 – Earn-Out Shares.

At December 31, 2021, the redeemable convertible preferred stock consisted of the following:

	Shares Authorized	Shares issued and outstanding	Liquidation amount
Series B Redeemable Convertible Preferred Stock	7,610,700	7,288,333	$ 26,237,999
Series A Redeemable Convertible Preferred Stock	26,250	26,245	26,245,000
Total	7,636,950	7,314,578	$ 52,482,999

The Company was authorized to issue 7,636,950 shares of all classes of preferred stock at a par value of $0.0001 per share as of December 31, 2021.

NOTE 13 - EARN-OUT SHARES

In connection with the Business Combination, certain of the Company's original stockholders are entitled to receive up to 3,000,000 Earn-out shares in three tranches:

(1) the first tranche of 1,000,000 Earn-out shares will be issued when the volume-weighted average price per share of PubCo common stock is $12.50 or greater for 20 trading days in any consecutive 30 trading day period commencing 6 months after the Closing and ending at the third anniversary of the Closing; ·

(2) the second tranche of 1,000,000 Earn-out shares will be issued when the volume-weighted average price per share of PubCo common stock is $15.00 or greater for 20 trading days in any consecutive 30 trading day period commencing 6 months after the Closing and ending at the third anniversary of the Closing; and ·

(3) the third tranche of 1,000,000 Earn-out shares will be issued when the volume-weighted average price per share of PubCo common stock is $17.50 or greater for 20 trading days in any consecutive 30 trading day period commencing 6 months after the Closing and ending at the third anniversary of the Closing.

The Earn-out shares will be allocated among the Company's stockholders in proportion to the number of shares issued to them at the closing that continue to be held by them.

Due to the variability in the number of Earn-out shares at settlement which could change upon a control event, the Earn-out arrangement contains a settlement provision that violates the indexation guidance under ASC 815-40 and liability classification is required. The Company recorded the earnout liability initially at fair value, and will subsequently remeasure the liability with changes in fair value recorded in the consolidated statement of operations.

The Company recorded an Earn-out liability of $22.07 million at issuance and a subsequent expense for change in fair value of Earn-out liability of $9.26 million as of December 31, 2022. The Earn-out liability as of December 31, 2022 was $12.81 million.

NOTE 14 — STOCK-BASED COMPENSATION

The Company issued 65,000 shares of restricted common C shares with a four- year vesting period during the year ended December 31, 2021; there were no issuances of restricted common C shares in the year ended December 31, 2022. 600,000 shares of the 2019 restricted common C shares vested upon consummation of the Business Combination on December 6, 2022. An additional 254,507 vested as per the vesting schedule, prior to consummation of the Business Combination.

A summary of non-vested restricted common C shares as of December 31, 2022 and changes during the year then ended is presented below:

	Shares	Weighted-Average Grant Date Fair Value per Share
Non-vested restricted common C shares as of December 31, 2021	912,692	$ 0.01
Granted	—	—
Vested	(854,507)	0.01
Forfeited	(58,185)	0.02
Non-vested restricted common C shares as of December 31, 2022	-	

A summary of non-vested restricted common C shares as of December 31, 2021 and changes during the year then ended is presented below:

	Shares	Weighted-Average Grant Date Fair Value per Share
Non-vested restricted common C shares as of December 31, 2020	1,370,391	$ 0.01
Granted	65,000	0.08
Vested	(381,689)	0.01
Forfeited	(141,010)	0.02
Non-vested restricted common C shares as of December 31, 2021(1)	912,692	$ 0.01

(1) As of December 31, 2021, there was $10,949 of total unrecognized compensation cost related to non- vested restricted common C shares that is expected to be recognized over a weighted-average period of 1.98 years. The estimated forfeiture rate for restricted common C share was 0% as of December 31, 2021.

The fair value of the 381,689 shares that vested during the year ended December 31, 2021 was approximately $4,100.

Total stock compensation expense for the years ended December 31, 2022 and 2021 was $2,156,915 and $4,712, respectively. Stock compensation expense related to the restricted common C shares was $11,915 and $4,712 for the years ended December 31, 2022 and 2021, respectively. Stock compensation expense related to the issuance of Series A Redeemable Convertible Preferred Stock to certain employees was $2,145,000 and $0 for the years ended December 31, 2022 and 2021, respectively. (See Note 12 – Redeemable Convertible Preferred Stock.)

For the year ended December 31, 2021, and until immediately prior to the Merger transaction, the fair values of the shares of the Company's restricted common C stock were estimated on each grant date by the board of directors. In order to determine the fair value, the then board of directors considered, among other things, valuations prepared by an independent third-party valuation firm in accordance with the guidance provided by the American Institute of Certified Public Accountants Practice Guide, Valuation of Privately-Held-Company Equity Securities Issued as Compensation. The fair value of the Company's restricted common C stock was estimated using a two-step process. First, the Company's enterprise value was established using generally accepted valuation methodologies, such as guideline public company and guideline company transactions. The enterprise value was allocated among the securities that comprise the capital structure of the Company using the option-pricing method. The option-pricing method treats all levels of the capital structure as call options on the enterprise's value, with exercise price based on the "breakpoints" between each of the different claims on the securities. The inputs necessary for the option-pricing model include the current equity value (the enterprise value as previously calculated), breakpoints (the various characteristics for each class of equity, including liquidation preferences and priority distributions, in accordance with the Company's certificate of incorporation, as amended and restated), term, risk-free rate, and volatility.

NOTE 15 — INCOME TAXES

The current tax expense for the years ended December 31, 2022 and 2021 was $6,480 and $7,652, respectively, which have been included in general and administrative expenses in the consolidated statements of operations. These amounts consisted of state and franchise tax expense.

A reconciliation of the federal income tax rate to the Company's effective tax rate as of December 31 is as follows:

	2022	2021
Statutory federal income tax rate	21.0 %	21.0 %
State taxes, net of federal tax benefit	24.7 %	8.0 %
PPP loan forgiveness	—	8.0 %
Stock Compensation	(6.3)%	— %
Transaction Costs	7.4 %	— %
Change in FV Earnout Liab.	27.2 %	— %
Change in FV of Debt	31.2 %	— %
Change in Warrant Liability	9.5 %	— %
Other Permanent Differences	(0.3)%	(0.5)%
Change in valuation allowance	(114.4)%	(36.5)%
Income tax provision	— %	— %

The tax effects of temporary differences that give rise to significant portions of the Company's deferred tax assets and liabilities as of December 31, 2022 and 2021 related to the following:

	2022	2021
Deferred tax assets		
Net operating losses	$ 17,847,721	$ 13,497,030
Reserve and accruals	619,236	554,632
OID Amortization	1,184,396	—
Debt Extinguishment Amortization	645,511	—
Debt-Related Warrants	1,408,206	
Capitalized R&D	557,589	—
Lease Liability	1,540,727	—
Other	1,388	1,792
Total deferred tax assets	23,804,774	14,053,454
Deferred tax liabilities		
Depreciation and amortization	(270,747)	(200,998)
Right of Use Asset	(1,511,785)	—
Total deferred tax liabilities	(1,782,533)	(200,998)
Net deferred tax assets	22,022,241	13,852,456
Valuation Allowance	(22,022,241)	(13,852,456)
Net deferred tax asset	**$ —**	**$ —**

Realization of deferred tax assets is dependent upon future pretax earnings, the reversal of temporary differences between book and tax income, and the expected tax rates in future periods. The Company records a valuation allowance to reduce deferred tax assets to the amount that is believed "more-likely-than-not" to be realized. The Company has recorded a full valuation allowance as of December 31,2022 and December 31, 2021. The change in the valuation allowance was an increase of $8,168,552 and $2,184,631 for the years ended December 31, 2022 and 2021, respectively.

As of December 31, 2022, the Company had net operating loss carryforwards for federal and state income tax purposes of approximately $70,812,501 and $43,017,282, respectively. Of the $70,812,501of net operating loss carryforwards for federal purposes, $35,193,226 have an unlimited carry-forward period. The remaining federal carryforwards begin to expire in 2028 while the state carryforwards begin to expire in 2036.

The Internal Revenue Code of 1986, as amended, imposes restrictions on the utilization of net operating losses in the event of an "ownership change" of a corporation. Accordingly, a company's ability to use net operating losses may be limited as prescribed under Internal Revenue Code Section 382 ("IRC Section 382"). Events which may cause limitations in the amount of the net operating losses that the Company may use in any one year include, but are not limited to, a cumulative ownership change of more than 50% over a three-year period. Utilization of the federal and state net operating losses may be subject to substantial annual limitation due to the ownership change limitations provided by the IRC Section 382 and similar state provisions. A detailed analysis to determine whether an ownership change under Section 382 has not been performed recently to determine if there is any limitation on the utilization of the company's net operating losses.

The Company performed a Section 382 analysis in 2017 and identified a change in ownership during 2017 and therefore a limitation in the ability to utilize the existing NOLs. The calculated limitation was $44M, and the DTA was reduced by the amount of the limitation that the Company will not be able to utilize in future tax periods. An updated Section 382 study has not been completed through December 31, 2022 and there has not been a determination if there is a cumulative ownership change of more than 50% during the most recent three-year period. The effect of a further Section 382 limitation on the provision and this disclosure is immaterial due to the full valuation allowance against all deferred tax assets, including NOLs, as of December 31, 2022.

The Company estimates that there will be no material changes in its uncertain tax positions in the next 12 months. In accordance with FASB ASC 740, the Company has adopted the accounting policy that interest and penalties recognized are classified as part of its income taxes. Total interest and penalties recognized in the consolidated statement of operations was zero 2022 and 2021.

The Company files income tax returns in the US federal, various state, and foreign jurisdictions with varying statutes of limitations. The Company is generally no longer subject to tax examinations for years prior to 2019 for federal purposes and 2018 for state purposes, except in certain limited circumstances. The Company's NOL and credit carryforwards from all years may be subject to adjustment for three (or four for certain states) following the year in which utilized. We do not anticipate that any potential tax adjustments will have a significant impact on our financial position or results of operations.

NOTE 16 — POST-RETIREMENT BENEFITS

The Company offers a 401(k) plan to employees and has historically matched employee contributions to the plan up to 3% of the employee's salary. The matching contributions accrued for the years ended December 31, 2022 and 2021 were $93,112 and $100,134, respectively.

NOTE 17 — NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS

The following table sets forth the computation of the basic and diluted net loss per share attributable to common stockholders during the years ended December 31:

	2022	2021
Numerator:		
Net loss attributable to common stockholders	$ (7,145,320)	$ (5,977,407)
Denominator:		
Weighted-average common shares outstanding	10,021,632	3,957,783
Net loss per share attributable to common stockholders, basic and diluted	$ (0.71)	$ (1.51)

The potential shares of common stock that were excluded from the computation of diluted net loss per share attributable to common stockholders for the years ended December 31, 2022 and 2021 because including them would have been antidilutive are as follows:

	2022	2021
Series A common stock upon conversion of redeemable convertible preferred stock A	—	4,214,422
Series A common stock upon conversion of redeemable convertible preferred stock B	—	7,288,333
Non-vested shares of Series C common stock	—	912,692
Senior and Subordinated Convertible Notes	3,179,410	—
Shares subject to warrants to purchase common stock	6,512,087	322,223
Total	9,691,497	12,737,670

NOTE 18 — SUBSEQUENT EVENTS

No subsequent event which had a material impact on the Company was identified through the date of issuance of the financial statements.

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 management, including our Chief Executive Officer and our Chief Financial Officer, conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as amended, as of the end of the period covered by this Annual Report on Form 10-K. Based on this evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures were not effective at the reasonable level of assurance due to a material weakness in internal control over financial reporting.

In connection with the audit of our financial statements as of and for the year ended December 31, 2022, we identified a material weakness in our internal control over financial reporting. The material weakness related to a lack of effective controls to adequately restrict access and segregate duties. Specifically, due to the staffing in our accounting function being limited in number and public company experience, the segregation of non-compatible responsibilities and reviews of the application of complex accounting were insufficient . Upon identifying this material weakness, we performed additional procedures to evaluate the impact on the financial statements. Based on these procedures, we believe the material weakness did not result in any material misstatements to our financial statements. However, this material weakness could result in a misstatement of our accounts or disclosures that would result in a material misstatement of our financial statements that would not be prevented or detected. We are implementing measures designed to improve our internal control over financial reporting to remediate this material weakness, including the following:

- We are in the process of adding additional accounting personnel with the requisite knowledge and experience in order to appropriately segregate duties amongst accounting personnel and address areas of complex accounting.
- We are evaluating our accounting system access rights so that there are accounting personnel without entry access who can perform review activities.
- We are formalizing our internal control documentation and strengthening supervisory reviews by our management.

We cannot assure you that the measures we have taken to date, and are continuing to implement, will be sufficient to remediate the material weakness we have identified or avoid potential future material weaknesses. If the steps we take do not correct the material weakness in a timely manner, we will be unable to conclude that we maintain effective internal control over financial reporting. Accordingly, there could continue to be a reasonable possibility that a material misstatement of our financial statements would not be prevented or detected on a timely basis.

Management's Report on Internal Control over Financial Reporting

This Form 10-K does not include a report of management's assessment regarding internal control over financial reporting or an attestation report from 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

There were no changes in our internal controls over financial reporting identified in management's evaluation pursuant to Rules 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the quarter ended December 31, 2022 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

Not applicable.

Item 9C. Disclosure Regarding Foreign Jurisdiction that Prevent Inspections

Not applicable.

PART III

Item 10. Directors, Executive Officers, and Corporate Governance

The information required by this Item will be included in our 2023 Proxy Statement, which will be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2022, and is incorporated herein by this reference.

Item 11. Executive Compensation

The information required by this Item will be included in our 2023 Proxy Statement, which will be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2022, and is incorporated herein by this reference.

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

The information required by this Item will be included in our 2023 Proxy Statement, which will be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2022, and is incorporated herein by this reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required by this Item will be included in our 2023 Proxy Statement, which will be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2022, and is incorporated herein by this reference.

Item 14. Principal Accountant's Fees and Services

The information required by this Item will be included in our 2023 Proxy Statement, which will be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2022, and is incorporated herein by this reference.

Part IV

Item 15. Exhibits and Financial Statement Schedules

EXHIBIT INDEX

Exhibit No.	Description
2.1	Merger Agreement dated May 9, 2022 (previously filed as Exhibit 2.1 of Form 8-K filed by Lakeshore with the SEC on May 10, 2022).
3.1	Amended and Restated Certificate of Incorporation of ProSomnus, Inc. (previously filed as Exhibit 3.1 of Form 8-K filed by ProSomnus with the SEC on December 13, 2022).
3.2	Amended and Restated Bylaws of ProSomnus, Inc. (previously filed as Exhibit 3.2 of Form 8-K filed by ProSomnus with the SEC on December 13, 2022).
4.1*	Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934
4.2	Specimen Common Stock Certificate (previously filed as Exhibit 4.1 of Form 8-K filed by ProSomnus with the SEC on December 13, 2022).
4.3	Specimen Warrant Certificate (included in Exhibit 4.3).
4.4	Warrant Agreement, dated June 10, 2021, by and between Continental Stock Transfer & Trust Company and the Registrant (previously filed as Exhibit 4.1 of Form 8-K filed by Lakeshore with the SEC on June 16, 2021).
10.1	Letter Agreement by and between the Registrant and each of the initial shareholders, officers and directors of the Registrant (previously filed as Exhibit 10.1 of Form 8-K filed by Lakeshore with the SEC on June 16, 2021).
10.2	Investment Management Trust Account Agreement, dated June 10, 2021, by and between Continental Stock Transfer & Trust Company and the Registrant (previously filed as Exhibit 10.2 of Form 8-K filed by Lakeshore with the SEC on June 16, 2021).
10.3	Registration Rights Agreement, dated June 10, 2021, among the Registrant, Continental Stock Transfer & Trust Company and the initial shareholders (previously filed as Exhibit 10.3 of Form 8-K filed by Lakeshore with the SEC on June 16, 2021).
10.4	Registration Rights Agreement, dated December 6, 2022, by and between ProSomnus, Inc. and parties thereto (previously filed as Exhibit 10.4 of Form 8-K filed by ProSomnus with the SEC on December 13, 2022).

10.5	Registration Rights Agreement, dated December 6, 2022, by and between ProSomnus, Inc. and certain holders of Convertible Notes (previously filed as Exhibit 10.5 of Form 8-K filed by ProSomnus with the SEC on December 13, 2022).
10.6	Form of Indemnification Agreement between ProSomnus, Inc. and certain of its officers and directors (previously filed as Exhibit 10.3 of Form 8-K filed by ProSomnus with the SEC on December 13, 2022).
10.7	Private Placement Securities Subscription Agreements by and between the Company and the purchasers of the Company's insider shares and private units (previously filed as Exhibit 10.5 of Form 8-K filed by Lakeshore with the SEC on June 10, 2021).
10.8	Form of Purchaser Support Agreement (previously filed as Exhibit 10.1 of Form 8-K filed by Lakeshore with the SEC on May 10, 2022).
10.9	Form of Voting and Support Agreement (previously filed as Exhibit 10.2 of Form 8-K filed by Lakeshore with the SEC on May 10, 2022).
10.10	Form of Lock-Up Agreement (previously filed as Exhibit 10.6 of Form 8-K filed by ProSomnus with the SEC on December 13, 2022).
10.11	Form of Non-Competition and Non-Solicitation Agreement (previously filed as Exhibit 10.4 of Form 8-K filed by Lakeshore with the SEC on May 10, 2022).
10.12	Form of Amended and Restated Registration Rights Agreement (previously filed as Exhibit 10.5 of Form 8-K filed by Lakeshore with the SEC on May 10, 2022).
10.13+	2022 Equity Incentive Plan (previously filed as Exhibit 10.2 of Form 8-K filed by ProSomnus with the SEC on December 13, 2022).
10.14	Indenture for Senior Secured Convertible Notes due 2025, dated December 6, 2022 by and between ProSomnus, Inc. and Wilmington Trust, National Association, as trustee and collateral agent (previously filed as Exhibit 10.9 of Form 8-K filed by ProSomnus with the SEC on December 13, 2022).
10.15	Indenture for Subordinated Secured Convertible Notes due 2026, dated December 6, 2022 by and between ProSomnus, Inc. and Wilmington Trust, National Association, as trustee and collateral agent (previously filed as Exhibit 10.10 of Form 8-K filed by ProSomnus with the SEC on December 13, 2022).
10.16	Employment Agreement with Leonard Liptak (previously filed as Exhibit 10.11 of Form 8-K filed by ProSomnus with the SEC on December 13, 2022).
10.17	Employment Agreement with Sung Kim (previously filed as Exhibit 10.14 of Form 8-K filed by ProSomnus with the SEC on December 13, 2022).
10.18	Employment Agreement with Melinda Hungerman (previously filed as Exhibit 10.13 of Form 8-K filed by ProSomnus with the SEC on December 13, 2022).
10.19	Employment Agreement with Laing Rikkers (previously filed as Exhibit 10.12 of Form 8-K filed by ProSomnus with the SEC on December 13, 2022).
14.1	Code of Ethics (previously filed as Exhibit 14.1 of Form S-1 - filed by ProSomnus with the SEC on January 9, 2023)
21.1	List of Subsidiaries of ProSomnus (previously filed as Exhibit 21.1 of Form 8-K filed by ProSomnus with the SEC on December 13, 2022).
23.1*	Consent of Marcum LLP
23.2*	Consent of Singer Lewak LLP
31.1*	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1*	Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101*	Inline XBRL data file.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

* Filed with this Annual Report on Form 10-K.
+ Indicates a management or compensatory plan.

Item 16. Form 10-K Summary

None.

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, on April 14, 2023.

PROSOMNUS, INC.

By: /s/ Len Liptak
Name: Len Liptak
Chief Executive Officer
Date: April 14, 2023

POWER OF ATTORNEY

Each person whose individual signature appears below hereby authorizes and appoints Len Liptak and Brian Dow and each of them, with full power of substitution and re-substitution and full power to act without the other, as his or her true and lawful attorney-in-fact and agent to act in his or her name, place, and stead and to execute in the name and on behalf of each person, individually and in each capacity stated below, and to file any and all amendments to this annual report on Form 10-K and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing, ratifying and confirming all that said attorneys-in-fact and agents or any of them or their or his substitute or substitutes may lawfully do or cause to be done by virtue thereof.

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 and on the dates indicated.

Signature	Title	Date
/s/ Len Liptak Name: Len Liptak	Chief Executive Officer (Principal Executive Officer)	April 14, 2023
/s/ Brian Dow Name: Brian Dow	Chief Financial Officer and Corporate Secretary (Principal Financial Officer and Principal Accounting Officer)	April 14, 2023
/s/ Laing Rikkers Name: Laing Rikkers	Executive Chair	April 14, 2023
/s/ Leonard Hedge Name: Leonard Hedge	Director	April 14, 2023
/s/ William Johnson Name: William Johnson	Director	April 14, 2023
/s/ Jason Orchard Name: Jason Orchard	Director	April 14, 2023
/s/ Steven Pacelli Name: Steven Pacelli	Director	April 14, 2023
/s/ Heather Rider Name: Heather Rider	Director	April 14, 2023

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Board of Directors

Laing Rikkers
Executive Chair

Len Liptak
Chief Executive Officer and Director

Len Hedge
Director

Bill Johnson
Director

Jason Orchard
Director

Steven Pacelli
Director

Heather Rider
Director

Management

Len Liptak
Chief Executive Officer

Laing Rikkers
Executive Chair

Sung Kim
Chief Technology Officer

Brian Dow
Chief Financial Officer

Mark Murphy, DDS
Chief Growth Officer

John E. Remmers, MD
Chief Scientist

Edward Sall, MD, DDS
Medical Director

PROSOMNUS®, INC.

5675 Gibraltar Drive
Pleasanton, CA 94588
USA

+1 844 537 5337
ProSomnus.com

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