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, 2023

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 (State of Other Jurisdiction of incorporation or Organization)	**88-2978216** (I.R.S. Employer Identification No.)
5675 Gibraltar Drive, Pleasanton, CA (Address of principal executive offices)	**94588** (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	☐	Non-accelerated filer	☒
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 aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant, based on the last sale price for such stock on June 30, 2023, was $25.7 million. This determination of affiliate status is not necessarily a conclusive determination for other purposes. As of March 25, 2024, there were 17,394,064 shares of Registrant's Common Stock outstanding.

Documents Incorporated by Reference

Portions of the company's Proxy Statement for the 2024 Annual Meeting of Stockholders are incorporated by reference in Part III.

TABLE OF CONTENTS

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:

- uncertainty of the projected financial information with respect to ProSomnus;
- ProSomnus's ability to continue as a going concern;
- ProSomnus's expectations regarding its ongoing review of financing and strategic alternatives;
- ProSomnus's ability to expand its sales network and product lines;
- ProSomnus's ability to maintain and grow its profit margin from sales of ProSomnus oral devices;
- ProSomnus's ability to expand internationally;
- the roll-out of ProSomnus's business and the timing of expected business milestones;
- ProSomnus's ability to formulate, implement and modify effective sales, marketing, and strategic initiatives to drive revenue growth;
- expectations concerning the effectiveness of OSA treatment using ProSomnus oral devices and the potential for patient relapse after completion of treatment;
- the understanding and adoption by dentists and other healthcare professionals of ProSomnus oral devices for mild-to-moderate OSA;
- ProSomnus's ability to attract and retain key personnel;
- the increased obligations related to being a public company;
- ProSomnus's ability to comply with its debt covenants or successfully renegotiating such covenants;
- ProSomnus's ability to obtain additional funding and preserve capital while it continues to assess potential strategic alternatives;
- ProSomnus's strategy, including significantly reducing its expenditures on operational and research and development activities and taking other cost savings measures in connection with its ongoing review of strategic alternatives;
- ProSomnus's plans and ability to regain compliance with the Nasdaq Listing Rules;
- the viability of ProSomnus's intellectual property and intellectual property created in the future;
- government regulations and ProSomnus's ability to obtain applicable regulatory approvals and comply with government regulations, including under healthcare laws and the rules and regulations of the U.S. Food and Drug Administration; and
- the outcome of any legal proceedings that may be instituted against ProSomnus.

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, Inc. and its consolidated subsidiaries.

Overview

We are a medical technology company focused on the development, manufacturing and marketing of precision intraoral medical devices, a novel non-invasive option for treating and managing patients with 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 oral 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 moves 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 250,000 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. 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.

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 with 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. Recently data presented from the 136 patient First Line Obstructive Sleep Apnea Treatment study ("FLOSAT") demonstrates that ProSomnus precision oral appliance therapy is effective, and non-inferior to CPAP, as a first-line treatment for moderate to severe OSA and, in an intention to treat analysis factoring efficacy and adherence, precision OAT (ProSomnus) demonstrated twice the mean disease alleviation as CPAP. 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, significantly 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 evaluating over 1,400 patients, indicate that ProSomnus devices are effective, efficacious, have an excellent demonstrated 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 200 million 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 practitioners and physician assistants who have undergone training in sleep medicine and oral appliance therapy.

We generated revenue of $27.7 million, with a net loss of $24.1 million, for the year ended December 31, 2023, compared to revenue of $19.4 million, with a net loss of $7.1 million, for the year ended December 31, 2022. 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 its sale in October 2016, accumulated deficit as of December 31, 2023 was $234.9 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 Pharmacopeia, 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. Further, recently presented data from the FLOSAT study demonstrated our therapy is effective and non-inferior to CPAP thus enabling 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 2017 order volumes have grown approximately 38% compounded annually. Over 250,000 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.

- **Strong customer metrics**. In 2023, we experienced a 96% retention rate among our top 100 customers, which are primarily sleep dentists, and a 33% increase in revenue from such customers. Our largest customer represents approximately 4.4% 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, HNS and other therapies, ProSomnus precision intraoral devices do not require highly invasive surgeries, or expensive ongoing consumables and device adjustments that are associated with CPAP, HNS and other treatment options.

  Our devices are reimbursable by many major commercial medical payors following a medical diagnosis of OSA. United Healthcare recognized the patient benefits and favorable economics when it updated its medical policy (#2024T0525NN) for Obstructive and Central Sleep Apnea, effective March 1, 2024. The updated policy established oral appliance therapy, such as ProSomnus's precision devices, as prerequisite therapy for Implantable Hypoglossal Nerve Stimulation. Specifically, the policy states, "Failure of adequate trial of Oral Appliance therapy," as the new medical policy of UHC. ProSomnus 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 with high 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. We are ISO 13485 certified demonstrating our ability to provide medical devices that consistently meet customer and applicable regulatory requirements.

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 marketing and sales of our ProSomnus intraoral devices in several European countries and intend to further expand our marketing and direct sales into other 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. During early 2024 we submitted to the U.S. FDA a 510(k) premarket notification for our ProSomnus EVO precision device for the treatment of patients with severe obstructive sleep apnea. This potential label expansion would increase the population of OSA patients and we can market our devices to by approximately 1.8 million patients.

- **Remote monitoring services**. We received FDA clearance for an intraoral device that enables remote patient monitoring services in November 2020. We are currently developing an advanced version of ProSomnus intraoral device enables remote patient monitoring, the $RPMO_2$ OSA Device, that will allow sleep providers the unique ability to monitor patient response, compliance and health. 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. 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.

- **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.

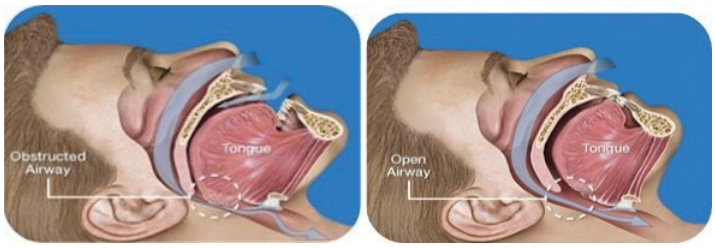
- **Severe OSA label expansion.** ProSomnus is currently working with the FDA to expand our labeling to include severe OSA. We are actively enrolling in our Severe Obstructive Sleep Apnea Study (SOS). The performance goals have been set with the FDA for the purpose of label expansion.

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 traditionally 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 by 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.

We are currently developing an advanced version of ProSomnus intraoral device, the $RPMO_2$ OSA Device, that will allow sleep providers the unique ability to monitor patient response, compliance and health. When used by a patient during sleep, the $RPMO_2$ OSA Device will monitor physiologic parameters including blood oxygen, heart rate, heart rate variability sleep apnea specific hypoxic burden and sleep apnea events. These physiological parameters have been found to be highly predictive of cardiovascular mortality. Through a Bluetooth connection to the patient's cellular phone, the $RPMO_2$ platform interfaces with the intraoral device, downloads monitored parameters data and transmits to a ProSomnus proprietary healthcare provider portal allowing providers access to patient specific treatment information. The RPMO2 OSA Device intraoral device has demonstrated that an oximeter embedded in a precision medical device can accurately, safely, and continuously monitor SpO2 in a recently completed pilot study. A larger follow-up study is planned for the first half of 2024, after successful completion of the study, will be followed by submitting to the U.S. FDA a 510(k) Premarket Notification planned for mid-2024.

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 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 over 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.
Syracuse	91		Company Supported	89% success all severities (AHI<10)	Sall E, Smith K, Desai A, et al. (December 07, 2023) Evaluating the Clinical Performance of a Novel, Precision Oral Appliance Therapy Medical Device Made Wholly From a Medical Grade Class VI Material for the Treatment of Obstructive Sleep Apnea. Cureus 15(12): e50107. doi:10.7759/cureus.50107

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.

An additional 91 patient study titled “Evaluating the Clinical Performance of a Novel, Precision Oral Appliance Therapy Medical Device Made Wholly from a Medical Grade Class VI Material for the Treatment of Obstructive Sleep Apnea,” (2023, Cureus 15(12): e50107. doi:10.7759/cureus.501070) demonstrated efficacy of ProSomnus devices treating patients with mild to severe OSA. During the study, 89% of all patients and 98.5% of mild to moderate OSA patients were treated to an AHI of fewer than 10 events per hour and 80% of severe OSA patients were treated to an AHI of fewer than 20 events per hour with a 50% improvement. In addition to the efficacy of ProSomnus devices, the study also demonstrated the 96% of patients continued using their ProSomnus device after a minimum one-year follow-up.

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.

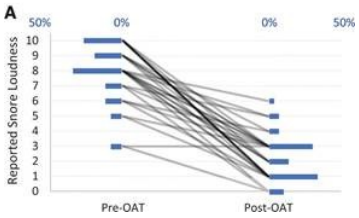
Patient Preference

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, otolaryngologist (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 also marketing and sales of our ProSomnus intraoral devices in several European countries including The Netherlands, Germany, Belgium, Switzerland and others.

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 plan to increase our count of direct sales representatives depending on our financial condition and availability of financial resources. Increasing the count of direct sales representatives is one of the main growth drivers for our long-term 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.

We have implemented 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 Healthcare Common Procedure Coding System ("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. We maintain an ISO 13485:2016 certified quality management system.

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.

Quality Management System

We are required to be in compliance with the Quality System regulations enforced by the FDA, and similar regulations enforced by other worldwide regulatory authorities. We maintain an ISO 13485:2016 certified quality management system. ISO 13485:2016 specifies requirements for a quality management system that are demonstrated by our ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements. We achieve this through 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.

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 $4.8 million and $3.0 million for the years ended December 31, 2023 and 2022, 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 and are now developing an advanced remote patient monitoring device the $RPMO_2$. 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 pharmaceutical 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 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 25, 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.

The ability of the FDA, foreign regulatory authorities and notified bodies to review and approve or certify new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies or notified bodies may also slow the time necessary for new medical devices and modifications to cleared or approved medical devices to be reviewed and/or cleared, approved or certified by necessary government agencies or notified bodies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Similarly, a prolonged government shutdown could prevent the timely review of our patent applications by the United States Patent and Trademark Office ("USPTO"), which could delay the issuance of any U.S. patents to which we might otherwise be entitled. Further, in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly fund our business.

In the EU, notified bodies must be officially designated to certify products and services in accordance with the EU Medical Devices Regulation. While several notified bodies have been designated, the COVID-19 pandemic significantly slowed down the designation process. Currently designated notified bodies have severe capacity constraints and are facing a large amount of requests for recertification of products under the MDR as a consequence of which review times have lengthened. This situation could significantly impact our ability to grow our business in the EU and EEA.

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.

Healthcare policy changes could harm our business, financial condition and results of operations.

In the U.S., there have been and continue to be a number of legislative initiatives to contain healthcare costs. The Affordable Care Act (the "ACA"), enacted in March 2010, made substantial changes in the way healthcare is financed by both governmental and private insurers. The ACA established a new Patient-Centered Outcomes Research Institute to oversee and identify priorities in comparative clinical effectiveness research, implemented payment system reforms, and expanded the eligibility criteria for Medicaid programs. Other legislative changes have been proposed and adopted since the ACA was enacted, which may impact our business, financial condition, and results of operations.

The expansion of the government's role in the U.S. healthcare industry may result in decreased profits, lower reimbursement by payors, and/or reduced medical procedure volumes, all of which may have a material adverse effect on our business, financial condition, and results of operations. We expect additional state, federal, and foreign healthcare policies and reform measures to be adopted in the future, any of which could limit reimbursement for healthcare products and services or otherwise result in reduced demand for our ProSomnus precision intraoral medical devices or additional pricing pressure, and have a material adverse effect on our industry generally and on our customers.

Any changes or uncertainty with respect to future coverage or reimbursement rates could affect demand for our ProSomnus precision intraoral medical devices, which in turn could impact our ability to successfully commercialize our products and could have a material adverse effect on our business, financial condition, and results 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.

Cybersecurity

Actual or attempted breaches of security, unauthorized disclosure of information, or denial of service attacks could result in significant harm to our business. We hold personal and/or other sensitive or confidential information, and any perception that this information is not secure could lead to substantial legal liability or damage to our reputation. Despite the implementation of security measures, our internal computer and information technology systems, as well as those of our vendors and customers, are vulnerable to attack and damage from computer viruses, malware, unauthorized access, denial of service attacks, or other harm. Threat actors seeking to cause disruption to our business pose a significant risk to our operations.

We face risks related to the protection of information that we maintain, or that we engage a third-party to maintain on our behalf. These risks include unauthorized access, acquisition, use, disclosure, or modification of such information. Cyberattacks are becoming increasingly frequent, sophisticated, and intense, and have become increasingly difficult to detect. These attacks could include the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering, and other means to affect service reliability and threaten the confidentiality, integrity, and availability of information.

A material cyberattack or security incident could cause interruptions in our operations, resulting in a material disruption of our business operations, damage to our reputation, financial condition, results of operations, cash flows, and prospects. Therefore, we continuously monitor our systems and implement security measures to protect against cyberattacks and other security threats.

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, 2023, we had 125 employees in North America, 2 in Canada and 9 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.

Risk Factor Summary

- **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.
    - We have a history of operating losses and may never achieve cash flow positive or profitable results of operations.
    - We can give no assurance that our internal and external sources of liquidity will be sufficient for our cash requirements.
    - If we are unable to obtain sufficient funding, we may be unable to execute our business plan and fund operations. We may not be able to obtain additional financing on commercially reasonable terms, or at all.

- We have engaged financial and legal advisors to identify and evaluate possible financial and strategic alternatives and their implications for ProSomnus.
- Because our business is not profitable, from time to time we may undergo a reduction in force to reduce our operating expenses. However, any corporate restructuring or headcount reduction may not result in anticipated savings, could result in total costs and expenses and attrition that are greater than expected and could disrupt our business.
- We have identified a historical material weakness in our internal control over financial reporting.
- 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).
- 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.

- **Risks Related to Intellectual Property**
  - We depend on our patents and proprietary technology, which we may not be able to protect.
  - We may face intellectual property infringement claims that would be costly to resolve.

- **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.
  - 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.
  - 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.
  - 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.

- **Risks Related to our Securities**
  - We are currently not in compliance with Nasdaq listing requirements, specifically those that require us to maintain a minimum market value of publicly held shares of at least $15.0 million and maintain a minimum market value of listed securities of at least $50.0 million and maintain a minimum bid price of at least $1.00. If we do not regain compliance with or continue to satisfy the Nasdaq continued listing requirements, our Common Stock could be delisted from Nasdaq.
  - Sales of a substantial number of shares of our securities in the public market could cause the price of our securities to fall.
  - There is no guarantee that our Warrants will be in the money, and they may expire worthless.
  - Servicing our existing and future debt, including the Convertible Notes, may require a significant amount of cash, and we may not have sufficient cash flow from our business to pay our indebtedness.
  - There can be no assurance that we will ever provide liquidity to our investors through a sale of our company.
  - If we were to dissolve, the holders of our securities may lose all or substantial amounts of their investments.

- **General Risk Factors**
    - Inadequate internal controls could result in inaccurate financial reporting.
    - We qualify as an "emerging growth company" and a "smaller reporting company" within the meaning of the Securities Act, and if we take advantage of certain exemptions from disclosure requirements available to emerging growth companies or smaller reporting 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 may become involved in litigation that may materially adversely affect us.

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, 2023 and 2022, we reported net losses of $24.1 million and $7.1 million, respectively, and negative cash flows from operating activities of $16.1 million and $10.2 million, respectively. Accumulated deficit as of December 31, 2023, was $234.9 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 our current level of expenditures and future cash flow projections, we believe having $6.4 million in unrestricted cash and cash equivalents will not be sufficient for the Company to continue operations as a going concern for at least one year from the issuance date of these consolidated financial statements. Additionally, the indentures governing our Convertible Notes contain monthly and quarterly financial covenants. Failure to comply with the covenants or obtain a waiver and extension from the holders of each series of our Convertible Notes could result in an event of default under each of the indentures governing our Convertible Notes and result in an acceleration of the Convertible Notes, which could have a material adverse effect on our business, financial condition and results of operations.

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.

We can give no assurance that our internal and external sources of liquidity will be sufficient for our cash requirements.

We must have sufficient sources of liquidity to fund our working capital requirements and execute on our strategic initiatives. Future new product launches or investments in other growth initiatives may demand increased working capital before any long-term return is realized from increased revenue. Our ability to achieve our business and cash flow plans is based on a number of assumptions which involve significant judgments and estimates of future performance, borrowing capacity and credit availability, and financing opportunities which cannot at all times be assured. Accordingly, there is no assurance that cash flows from operations and other internal and external sources of liquidity will at all times be sufficient for our cash requirements, including repayment of debt. If necessary, we may need to consider actions and steps to improve our cash position and mitigate any potential liquidity shortfall, such as modifying our business plans, pursuing additional financing to the extent available, reducing capital expenditures, suspending certain activities or programs, pursuing and evaluating other alternatives and opportunities to obtain additional sources of liquidity, and other potential actions to reduce costs. There can be no assurance that any of these actions would be successful, sufficient or available on favorable terms. Any inability to generate or obtain sufficient levels of liquidity to meet our cash requirements at the level and times needed could have a material adverse impact on our business and financial position.

If we are unable to obtain sufficient funding, we may be unable to execute our business plan and fund operations. We may not be able to obtain additional financing on commercially reasonable terms, or at all.

We have experienced operating losses and we may continue to incur operating losses for the next several years as we implement our business plan. Our prior losses, combined with expected future losses, have had, and will continue to have, for the foreseeable future, an adverse effect on our stockholders' equity and working capital.

We will need to raise additional capital in order to continue to execute our business plan. If we are unable to raise sufficient additional funds, we may need to scale back our future operations. We cannot give any assurance that we will be able to obtain all the necessary funding that we may need. In addition, we believe that we will require additional capital in the future to fully develop and bring to market our technologies and planned products.

If we raise funds by issuing equity or equity-linked securities, dilution to some or all our stockholders would result. Any equity securities issued may also provide for rights, preferences or privileges senior to those of holders of our common stock. The terms of debt securities issued or borrowings could impose significant restrictions on our operations. We also may seek government-based financing, such as development and research grants. There can be no assurance that funds will be available on commercially reasonable terms, if at all.

Any future indebtedness could impose on us restrictive covenants, including, further limitations on our ability to incur additional debt, limitations on our ability to issue additional equity, limitations on our ability to acquire or license intellectual property rights, and other operating restrictions that could adversely affect our ability to conduct our business. In addition, the issuance of additional equity securities by us, or the possibility of such issuance, may cause the market price of our common stock to decline.

If we are unable to obtain adequate financing or financing on terms satisfactory to us when we require it, we may be required to, among other things, delay, scale back or eliminate some or all of our activities, reduce headcount, trim research and product development programs, discontinue clinical trials, stop all or some of our manufacturing operations, defer capital expenditures, deregister from being a publicly traded company and delist from Nasdaq, or license our potential products or technologies to third parties, possibly on terms that cannot sustain our current business, or curtail, suspend or discontinue our operations entirely. If any of these things were to occur, our ability to grow and support our business and to respond to market challenges could be significantly limited or we may be unable to continue operations, in which case you could lose your entire investment.

We have engaged financial and legal advisors to identify and evaluate possible financial and strategic alternatives and their implications for ProSomnus.

We engaged financial and legal advisors to identify and evaluate possible financial and strategic alternatives and their implications for ProSomnus. No assurance can be given as to whether any particular recommended financial or strategic alternative will be undertaken, and if so, upon what terms or conditions. We may not have enough available cash to purse a strategic restructuring, refinancing, or other transaction, and may have to file for bankruptcy. Bankruptcy, whether Chapter 11 or Chapter 7, could result in significant decrease in value for all stakeholders. In addition, if we file for bankruptcy, it may cause disruption in supply from critical vendors required to continue operations, negatively impact sales orders and collections from customers and negatively impact employee relations.

Because our business is not profitable, from time to time we may undergo a reduction in force to reduce our operating expenses. However, any corporate restructuring or headcount reduction may not result in anticipated savings, could result in total costs and expenses and attrition that are greater than expected and could disrupt our business.

If we decide to further reduce headcount to lower our operating expenses, we may not realize, in full or in part, the anticipated benefits, savings and improvements in our cost structure from such a restructuring because of unforeseen difficulties, delays or unexpected costs. If we are unable to realize the expected operational efficiencies and cost savings from such a restructuring, our operating results and financial condition would be adversely affected. Any restructuring activities would be disruptive to our operations and could result in material delays in our new product development programs. Headcount reductions could yield unanticipated consequences, such as attrition beyond planned staff reductions, or increase difficulties in our day-to-day operations. Headcount reductions could also harm our ability to attract and retain qualified management, scientific, clinical, regulatory, manufacturing, engineering, and other personnel who are critical to our business. Any failure to attract or retain qualified personnel could prevent us from successfully developing and commercializing our new product candidates in the future.

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

In connection with the audits of our consolidated financial statements for the years ended December 31, 2023 and 2022, 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 ability to use our net operating losses and research and development credit carryforwards to offset future taxable income may limited, perhaps substantially.

In general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (or the Code), a corporation that undergoes an "ownership change," generally defined as a greater than 50% change by value in its equity ownership over a three-year period, is subject to limitations on its ability to utilize its pre-change net operating losses ("NOLs"), carryforwards to offset future taxable income. Our existing NOLs may be subject to limitations arising from previous ownership changes. If we undergo, or are deemed to have previously undergone, an ownership change, our ability to utilize NOLs carryforwards could be limited (perhaps substantially) by Sections 382 and 383 of the Code. Additionally, future changes in our stock ownership, some of which might be beyond our control, could result in an ownership change under Section 382 of the Code. For these reasons, in the event we experience or are deemed to have experienced an "ownership change" for these purposes, we may not be able to utilize a material or even a substantial portion of the NOLs carryforwards, even if we attain profitability. We have not completed a Code Section 382 analysis regarding any limitation on our NOL carryforwards.

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 Europe and 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.

Performance issues, service interruptions or price increases by our primary shipping carrier could increase our shipping costs, adversely affect our business and harm our reputation and ability to provide our services on a timely basis.

Expedited and reliable shipping is a crucial component of our business operations. We heavily rely on our primary shipping carrier for secure and timely transport of our products to our customers. Any performance issues, such as delivery delays, loss, or damage of our products during transit, could harm our reputation and lead to decreased demand for our services. Additionally, any service interruptions, such as strikes, severe weather, or natural disasters, could adversely affect our ability to process orders and deliver our products on time. Furthermore, any price increases by our primary shipping carrier could increase our shipping costs and negatively impact our business operations.

We are subject to operating risks, including excess or constrained capacity and operational inefficiencies, which could adversely affect our results of operations.

Our business operations are subject to various operating risks, including excess or constrained capacity, pressure on our internal systems, personnel, and suppliers, and operational inefficiencies. To manage our current and anticipated future operations effectively, we must continually implement and improve our operational, financial, and management information systems, hire, train, motivate, manage, and retain employees, and ensure that our suppliers remain diverse and capable of meeting growing demand for the systems, raw materials, parts, and components essential to the manufacture and delivery of our products. However, we may be unable to balance near-term efforts to meet existing demand with future customer demand, including adding personnel, creating scalable, secure, and robust systems and operations, and automating processes needed for long-term efficiencies. Any such failure could have a material impact on our business, operations, and prospects.

Our ability to obtain and maintain regulatory clearance and certifications and equip facilities is subject to significant risk and uncertainty. If a facility is temporarily or permanently, partially or fully shut down, or if demand for our products outpaces our ability to hire qualified personnel and effectively implement systems and infrastructure, we may be unable to fulfill orders timely or at all, which may negatively impact our financial results, reputation, and overall business. Therefore, we must continuously monitor and manage our operations to minimize these risks and ensure our ability to meet the demands of our customers.

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.

Third-party payors often require billing clinicians to participate in the third-party payors network ("in-network") to receive the maximum benefit from the third-party payor. If our customer dentists and clinicians do not participate in third-party payor networks, costs to patients may increase materially and adversely and negatively impact our business by reducing patient willingness to pay out of pocket for our products resulting in reduced revenue.

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.

If our facilities are damaged or become inoperable, we may be unable to supply our ProSomnus devices and, as a result, there could be an adverse effect on our business until we are able to secure a new facility and rebuild our inventory.

Our business operations heavily rely on our facilities to manufacture and supply our ProSomnus devices. We do not have redundant facilities, and we perform all of our manufacturing and back-office activities at a single location. In the event of any natural or man-made disasters, such as fire, flooding, power outages, or public health crises, our facilities and inventory could be damaged or rendered inoperable, making it difficult or impossible for us to manufacture and supply our ProSomnus devices. The inability to perform these activities could result in the loss of customers and harm to our reputation. Although we possess insurance for damage to our property and the disruption of our business, this insurance may not be sufficient to cover all of our potential losses, and it may not continue to be available to us on acceptable terms or at all.

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.

In addition to patent protection for our issued patents and pending patent applications related to our ProSomnus precision intraoral medical devices and our manufacturing process, we also rely upon copyright and trade secret protection, as well as non-disclosure agreements and invention assignment agreements with our employees, consultants, and third parties, to protect our confidential and proprietary information. We implement commonly accepted physical and technological security measures to protect the confidential nature of our proprietary information.

However, these measures may not provide adequate protection against challenges to the validity and enforceability of our patents, or against unauthorized use or disclosure of our proprietary information by third parties. Our security measures may not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our products that we consider proprietary.

Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive, and time-consuming, and the outcome is unpredictable. Even though we use commonly accepted security measures, trade secret violations are often a matter of state law, and the criteria for protection of trade secrets can vary among different jurisdictions. In addition, trade secrets may be independently developed by others in a manner that could prevent legal recourse by us.

If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, our business and competitive position could be harmed. Therefore, we must continually monitor and manage our intellectual property to minimize these risks and ensure our ability to protect our proprietary technologies and know-how.

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 unable to enforce our intellectual property rights throughout the world.

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the U.S. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. This could make it difficult for us to stop infringement of our foreign patents, if obtained, or the misappropriation of our other intellectual property rights. For example, some foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, some countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Patent protection must ultimately be sought on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries.

Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. In addition, changes in the law and legal decisions by courts in the U.S. and foreign countries may affect our ability to obtain adequate protection for our technology and the enforcement of our intellectual property.

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.

If we do not obtain and maintain international regulatory registrations, approvals or certifications for our products, we will be unable to market and sell our products outside of the U.S.

Sales of our products outside of the U.S. are subject to foreign regulatory requirements that vary widely from country to country. In addition, the FDA regulates exports of medical devices from the U.S. While the regulations of some countries may not impose barriers to marketing and selling our products or only require notification, others require that we obtain the approval of or certification by a specified body (e.g., notified bodies in Europe). Complying with foreign regulatory requirements, including obtaining registrations, approvals or certifications, can be expensive and time-consuming, and we may not receive regulatory approvals or certifications in each country in which we plan to market our products or we may be unable to do so on a timely basis. The time required to obtain registrations, approvals or certifications, if required by other countries, may be longer than that required for FDA approval, and requirements for such registrations, clearances, approvals or certifications may significantly differ from FDA requirements. If we modify our products, we may need to apply for additional regulatory approvals or certifications before we are permitted to sell the modified product. In addition, we may not continue to meet the quality and safety standards required to maintain the authorizations or certifications that we have received. If we are unable to maintain our authorizations or certifications in a particular country, we will no longer be able to sell the applicable product in that country.

Risks Related to our Securities

If we do not regain compliance with or continue to satisfy the Nasdaq continued listing requirements, our Common Stock could be delisted from the Nasdaq.

The listing of our Common Stock on the Nasdaq Global Market ("Nasdaq") is contingent on our compliance with the Nasdaq's conditions for continued listing. We are currently not in compliance with Nasdaq listing requirements, specifically those that require us to maintain a minimum market value of publicly held shares of at least $15.0 million and maintain a minimum market value of listed securities of at least $50.0 million and maintain a minimum bid price of at least $1.00. On February 12, 2024 and March 19, 2024, we received delisting determination letters from Nasdaq advising us that we did not regain compliance with the minimum market value of publicly held shares requirement and the minimum bid price requirement by the initial compliance dates afforded by Nasdaq. As a result, trading of our securities on Nasdaq was subject to suspension at the opening of business on February 22, 2024 and a Form 25-NSE would have been filed with the SEC to remove our securities from listing and registration on the Nasdaq unless we requested an appeal of these determinations to a Nasdaq Hearings Panel (the "Panel"). On February 16, 2024, we submitted a hearing request to the Panel to appeal the delisting determinations. Our request for a hearing has stayed the suspension of our securities and the filing of a Form 25-NSE pending the Panel's decision. At the hearing, we intend to present a plan to regain compliance with the minimum market value of publicly held securities requirement and the minimum bid price requirement regardless of the outcome of the hearing, we must also

regain compliance with the minimum market value of listed securities requirement by April 30, 2024. If we are unable to regain such compliance, we will cease to be eligible to trade on Nasdaq and will likely be delisted by Nasdaq.

If the Panel does not grant our request for continued listing, or otherwise provide a further extension for us to regain compliance with the minimum market value of publicly held shares requirement or the minimum bid price requirement, our securities will be subject to delisting by Nasdaq. In the event our Common Stock is no longer listed for trading on Nasdaq, our trading volume and share price may decrease, and we may experience further difficulties in raising capital, which could materially affect our operations and financial results. Further, delisting from the Nasdaq could also have other negative effects, including potential loss of confidence by partners, lenders, suppliers and employees and could also trigger various defaults under our financing arrangements and other outstanding agreements. For instance, under our Convertible Notes, the occurrence of a delisting event could constitute a fundamental change (as defined in each indenture governing our Convertible Notes), giving holders of the Convertible notes the right to require us to repurchase all or a portion of their Convertible Notes before the applicable maturity date of such Convertible Notes at a repurchase price equal to 101% of the principal amount of the Convertible Notes to be repurchase, plus accrued and unpaid interest, if any. See the risk factor entitled "We may not have the ability to raise the funds necessary to repurchase the Convertible Notes upon a fundamental change or make mandatory redemptions of certain of the Convertible Notes pursuant to their terms, and our future debt may contain limitations on our ability to repurchase the Convertible Notes." Finally, delisting could make it harder for us to raise capital and sell securities. You may experience future dilution as a result of future equity offerings. In order to raise additional capital, we may in the future offer additional shares of our Common Stock or other securities convertible into or exchangeable for our Common Stock.

The Convertible Notes contain financial and operating covenants which could result in an event of default under the Convertible Notes.

Our failure to comply with the financial and operating covenants in our Convertible Notes could result in an event of default which, if not cured or waived, could result in the acceleration of the Convertible Notes, including via cross-defaults. For example, our Convertible Notes are subject to a financial covenant that requires us to maintain a minimum cash balance of $4.5 million on the first day of each calendar month. Failure to comply with the covenants or obtain a waiver and extension from the holders of each series of our Convertible Notes could result in an event of default under each of the indentures governing our Convertible Notes and result in an acceleration of the Convertible Notes, which could have a material adverse effect on our business, financial condition and results of operations.

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

Based on their holdings as of December 31, 2023, our directors and executive officers and their affiliates as a group beneficially owned approximately 11.9% 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, 2023, we had 17,388,599 outstanding shares of Common Stock, and our total number of warrants is 11,966,611, out of which 6,512,087 warrants are exercisable to our common stock at $11.50 per share. The remaining 5,454,524 warrants represent transaction warrants, which are exercisable to our Common Stock at $1.00 per share.

In addition, as of December 31, 2023, we have the following additional shares of Common Stock issuable:

- 5,889,525 shares of Common Stock reserved for issuance under our 2022 Equity Incentive Plan (the "2022 Equity Incentive Plan");
- 1,562,497 shares of our Common Stock issuable upon the exercise of outstanding options under the 2022 Equity Incentive Plan, with a weighted average exercise price of $4.67 per share;
- 543,750 shares of our Common Stock issuable upon the vesting of outstanding restricted stock units granted under the 2022 Equity Incentive Plan;

- the issuance of shares of our Common Stock that may be issuable as dividends in respect of our Series A Preferred Stock;
- the issuance of 15,766,509 shares of our Common Stock that may be issuable upon conversion of our convertible notes;
- 9,436,000 shares of our Common Stock issuable upon the exercise of our Series A Preferred Stock;
- the potential issuance of up to 3,000,000 shares of Common Stock issuable in satisfaction of our earnout obligations from our business combination with Lakeshore Acquisition I Corp. ("Lakeshore") on December 6, 2022 (the "Business Combination"); and

To the extent any or all such shares of Common Stock are issued, such additional shares of Common Stock will result in dilution to the holders of our Common Stock and increase the number of shares eligible for resale in the public market.

Our registration statements filed with the SEC register shares of our Common Stock issuable upon exercise of warrants and the offering and resale of our Common Stock by the selling securityholders. Such selling securityholders will determine the timing, pricing and rate at which they sell the shares being registered for resale into the public market. Significant sales of shares of Common Stock may have negative pressure on the public trading price of our Common Stock 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.

Furthermore, pursuant to the registration rights agreement entered into in connection with the Business Combination, 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 also granted the certain registration rights to the investors party to the Securities Purchase Agreement. We have filed and intend to maintain the registration statement in order to facilitate registration of those sales. The registration of these securities permits the exercise of such securities or the public resale of such securities, as applicable. 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.

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

As of December 31, 2023, we have 6,512,087 warrants to purchase Common Stock, which are exercisable at a price of $11.50 per share, and 5,454,524 Transaction Warrants to purchase Common Stock, exercisable at a price of $1.00 per share, outstanding. The likelihood that the holders of the Transaction Warrants or the other warrants will exercise their respective 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 Transaction Warrants and our other warrants. If the market price of our Common Stock continues to be less than the exercise price, it is unlikely that holders will exercise such warrants, and therefore unlikely that we will receive any proceeds from the exercise of such warrants 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, 2023, we are authorized to issue 151,500,000 shares of capital stock, of which 150,000,000 shares are authorized as Common Stock and 1,500,000 shares are authorized as Preferred Stock. The Company's stockholders approved an amendment to the Company's Amended and Restated Certificate of Incorporation on December 6, 2023. This amendment increased the number of authorized shares from 101,000,000 shares to 151,500,000 shares. Our Board of Directors, without any action by our stockholders, has and may again 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 have and 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.

Specifically, pursuant to the Securities Purchase Agreement, we issued an aggregate of 10,426 shares of Series A Preferred Stock. With respect to any matter submitted to the vote of the holders of Common Stock, the holders of the Series A Preferred Stock are entitled to vote the whole number of votes equal to the number of shares of Common Stock into which such holder's Series A Preferred Stock would be convertible on the record date for the vote or consent of stockholders at a conversion price of $1.04 per share of Common Stock rounded to the nearest whole share together, subject to certain limitations. The Series A Preferred Stock also ranks senior to the Common Stock and any other *pari passu* capital stock of the Company with respect to dividends, distributions and payments upon a liquidation event. Furthermore, the Series A Preferred Stock is convertible into Common Stock, subject to certain limitations, at a rate of 1,000 shares of Common Stock per one share of Series A Preferred Stock.

Servicing our existing and future debt, including the Convertible Notes, may require a significant amount of cash, and we may not have sufficient cash flow from our business to pay our indebtedness.

As of December 31, 2023, after giving effect to the in-kind interest payment on such date, we had approximately $36.8 million aggregate principal amount of the Convertible Notes outstanding. Our ability to make scheduled payments of the principal of, to pay interest on, or to refinance our indebtedness, including the Convertible Notes, depends on our future performance, which is subject to economic, financial, competitive, and other factors beyond our control. Our business may not generate cash flow from operations in the future sufficient to service our debt and make necessary capital expenditures. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt, or obtaining additional debt financing or equity capital on terms that may be onerous or highly dilutive. Our ability to refinance any future indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations. In addition, any of our future debt agreements may contain restrictive covenants that may prohibit us from adopting any of these alternatives. Our failure to comply with these covenants could result in an event of default which, if not cured or waived, could result in the acceleration of our debt.

In addition, our indebtedness, combined with our other financial obligations and contractual commitments, could have other important consequences. For example, it could:

- make us more vulnerable to adverse changes in general U.S. and worldwide economic, industry, and competitive conditions and adverse changes in government regulation;
- limit our flexibility in planning for, or reacting to, changes in our business and industry;
- place us at a disadvantage compared to our competitors who have less debt;
- limit our ability to borrow additional amounts to fund acquisitions, for working capital, and for other general corporate purposes; and
- make acquiring us less attractive or more difficult.

Any of these factors could harm our business, results of operations, and financial condition. In addition, if we incur additional indebtedness, the risks related to our business and our ability to service or repay our indebtedness would increase.

We may not have the ability to raise the funds necessary to repurchase the Convertible Notes upon a fundamental change or make mandatory redemptions of certain of the Convertible Notes pursuant to their terms, and our future debt may contain limitations on our ability to repurchase the Convertible Notes.

Holders of the Convertible Notes have the right to require us to repurchase all or a portion of their Convertible Notes of the applicable series upon the occurrence of a fundamental change (as defined in the applicable indenture governing such series of Convertible Notes) before the applicable maturity date at a repurchase price equal to 101% of the principal amount of the Convertible Notes to be repurchased, plus accrued and unpaid interest, if any. Additionally, we are required to make mandatory redemptions of a portion of our Senior Secured Convertible Notes due December 6, 2025 (the "Senior Convertible Notes") on a quarterly basis. Moreover, we will be required to repay the Convertible Notes in cash at their maturity unless earlier converted, redeemed or repurchased. However, we may not have enough available cash or be able to obtain financing at the time we are required to make repurchases or redemptions of Convertible Notes pursuant to their terms or pay cash with respect to Convertible Notes at their maturity.

In addition, our ability to repurchase Convertible Notes or to pay cash at their maturity may be limited by law, regulatory authority or agreements governing our future indebtedness. Our failure to repurchase the Convertible Notes when the repurchase is required by the applicable indenture or to pay cash at their maturity as required by such indenture would constitute a default under such indenture. A default under the indenture governing a series of Convertible Notes or the fundamental change itself could also lead to a default under agreements governing our existing and future indebtedness. If the payment of the Convertible Notes were to be accelerated after any applicable notice or grace periods, we may not have sufficient funds to repay the indebtedness. Any failure by us to repay indebtedness and repurchase the Convertible Notes, in each case, when required to do so pursuant to the terms of the applicable indenture, could have a material adverse effect on our business, financial condition, and results of operations.

Transactions relating to the Convertible Notes may affect the value of our Common Stock.

The Convertible Notes are convertible, in whole or in part, at any time at the election of the holders. The conversion of some or all of the Convertible Notes would dilute the ownership interests of our existing stockholders.

We have not paid cash dividends on our capital stock, and we do not anticipate paying cash dividends in the foreseeable future.

We have never paid cash dividends on any of our capital stock and we currently intend to retain any future earnings to fund the growth of our business. Any determination to pay cash 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 of Directors 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, but are not limited to:

- 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 and the exercise or conversion of our outstanding warrants and shares of Series A Preferred Stock; 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 other than the Transaction Warrants prior to their exercise at a time that is disadvantageous to you, thereby making your warrants worthless.

We may redeem outstanding warrants other than the Transaction 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 other than the Transaction 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.

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 such 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.

We do not know whether an active, liquid and orderly trading market will exist for our common stock and as a result it may be difficult for you to sell your common stock.

Prior to our combination with Lakeshore Acquisition I Corp and its wholly-owned subsidiary in December 6, 2022, there was no public market for our common stock. Although our common stock is listed on The Nasdaq Capital Market ("Nasdaq"), the market for our shares has demonstrated varying levels of trading activity. As a result of these and other factors, you may not be able to sell your common stock quickly, at or above the price paid to acquire the stock or at all. Further, an inactive market may also harm our ability to raise capital by selling additional common stock and may harm our ability to enter into strategic collaborations or acquire companies or products by using our common stock as consideration.

If we were to dissolve, the holders of our securities may lose all or substantial amounts of their investments.

If we were to dissolve as a corporation, as part of ceasing to do business or otherwise, we may be required to pay all amounts owed to any creditors before distributing any assets to the investors. There is a risk that in the event of such a dissolution, there will be insufficient funds to repay amounts owed to holders of any of our indebtedness and insufficient assets to distribute to our other investors, in which case investors could lose their entire investment.

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 Chief Executive Officer, Chief Financial Officer and our Chief Technology Officer. 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 recently 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.

Changes in, or interpretations of, accounting rules and regulations, could result in unfavorable accounting charges.

We prepare our consolidated financial statements in conformity with U.S. GAAP. These principles are subject to interpretation by the SEC and various bodies formed to interpret and create appropriate accounting policies. A change in these policies or in the way these policies are interpreted by us or regulators could have a material effect on our reported results and may even retroactively affect previously reported financial statements.

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" and a "smaller reporting company" within the meaning of the Securities Act, and if we take advantage of certain exemptions from disclosure requirements available to emerging growth companies or smaller reporting 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.

Additionally, we qualify as a "smaller reporting company" as defined in Item 10(f)(1) of Regulation S-K. Smaller reporting companies may take advantage of certain reduced disclosure obligations, including, among other things, providing only two years of audited financial statements. We expect to remain a smaller reporting company until the last day of the fiscal year in which (i) the market value of our Common Stock held by non-affiliates exceeds $250,000,000 as of the prior June 30, or (ii) our annual revenues exceeded $100,000,000 during such completed fiscal year and the market value of our Common Stock held by non-affiliates exceeds $700,000,000 as of the prior June 30. To the extent we take advantage of such reduced disclosure obligations, comparison of our financial statements with other public companies may be difficult or impossible.

We may become involved in litigation that may materially adversely affect us.

The Company faces a variety of litigation risks that may arise in the normal course of its business, including product liability litigation risk, employment litigation, and intellectual property litigation risk. In addition, the Company may be involved in claims, lawsuits, investigations, or proceedings related to securities laws, patent infringement, contract disputes, and other matters. Third parties may also assert claims against the Company, which can be time-consuming, divert management's attention and resources, cause significant expenses or liability, and/or require changes in business practices.

Due to the potential risks, expenses, and uncertainties of litigation, the Company may settle disputes, even where it has meritorious claims or defenses, by agreeing to settlement agreements. Litigation is inherently unpredictable, and the results of any legal proceedings may have a material adverse effect on the Company's business, financial condition, results of operations, and prospects. The Company cannot assure investors that the results of any legal proceedings will not have a material adverse effect on the business. For more detail on the Company's current legal proceedings, please refer to the section entitled "Legal Proceedings."

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

The Company's Board of Directors (the "Board") recognizes the critical importance of maintaining the trust and confidence of our customers, clients, business partners and employees. The Board is actively involved in the oversight of the Company's risk management program, and cybersecurity represents an important component of the Company's overall approach to enterprise risk management ("ERM").

Risk Management and Strategy

As one of the critical elements of the Company's overall ERM approach, the Company's cybersecurity program is focused on the following key areas:

- **Governance and Cybersecurity Testing**: The Board's oversight of cybersecurity risk management is supported by the Company's Chief Technology Officer ("CTO"). The Company is in the process of strengthening the periodic assessment and testing of the Company's policies, standards, processes and practices that are designed to address cybersecurity threats and incidents. These efforts include a wide range of activities, including audits, assessments, vulnerability testing and other exercises focused on evaluating the effectiveness of our cybersecurity measures and planning. The Company engages third parties to perform assessments on our cybersecurity measures, including information security maturity assessments, audits and independent reviews of our information security control environment and operating effectiveness. The results of such assessments, audits and reviews are reported to our CTO, and the Company adjusts its cybersecurity policies, standards, processes and practices as necessary based on the information provided by these assessments, audits and reviews.
- **Technical Safeguards:** The Company deploys technical safeguards that are designed to protect the Company's information systems from cybersecurity threats, including firewalls, intrusion prevention and detection systems, anti-malware functionality and access controls, which are evaluated and improved through vulnerability assessments and cybersecurity threat intelligence.
- **Incident Response and Recovery Planning:** The Company currently relies on an established major incident management and communication process to address any potential cybersecurity incidents. This established process includes the use of third-party partnerships to make available the distinct skill sets needed to assist in properly responding to any cybersecurity threat. The Company is in the process of establishing defined response procedures to effectively address any cyber threat that may occur regardless of the safeguards in place that minimize the chance of a successful cyberattack. The response procedures will be designed to identify, analyze, contain and remediate such cyber incidents expeditiously. These procedures and approach to safeguard the Company's information and assets will be continuously monitored by management and updated to evolve with the current cyber landscape.

Cybersecurity threats, including as a result of any previous cybersecurity incidents, have not materially affected or are reasonably likely to affect the Company, including its business strategy, results of operations or financial condition.

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. On February 28, 2023, the Company abandoned the office premises located 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 expired 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 25, 2024, there were 363 holders of record of our Common Stock and 37 holders of record of our warrants.

Recent Sales of Unregistered Securities

On September 20, 2023, the Company entered into a Securities Purchase Agreement (the “Securities Purchase Agreement”, and the transactions contemplated by the Securities Purchase Agreement, the “Financing Transaction”) with certain third-party and related party investors (the “Investors”), pursuant to which the Company issued (i) an aggregate of 10,426 shares of the Company’s Series A Preferred Stock, par value $0.0001 per share (the “Series A Preferred Stock”), for an aggregate purchase price of $10.4 million at a per share purchase price of $1,000, and (ii) (A) with respect to Investors that held the Existing Convertible Notes, new convertible notes on substantially similar terms to such Noteholder Investor’s Existing Convertible Notes other than that such new notes will be convertible into shares of Common Stock, at a conversion price of $1.00 per share subject to the terms and conditions of the applicable new indenture pursuant to which the applicable series of New Notes have been issued by the Company (the “New Notes”), in exchange for such Noteholder Investor’s portion of the principal amount outstanding of the Existing Notes (the “Exchanges”) pursuant to exchange agreements entered into between the Company and each of the Noteholder Investors (together, the “Exchange Agreements”) and/or (B) warrants to purchase shares of Common Stock at an exercise price of $1.00 per share (such warrants, the “Transaction Warrants”). The Financing Transaction closed on three dates: September 20, 2023, September 26, 2023, and October 20, 2023. The exchange of the Existing Convertible Notes, including the entrance into the indentures governing the New Notes, occurred on October 11, 2023.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Item 6. [Reserved]

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, 2023 and 2022, 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 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 250,000 ProSomnus precision devices have been prescribed for patients.

Sleep apnea is a serious and chronic respiratory disease that negatively impacts a patient's sleep, 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 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 dental products. Surgical procedures, such as hypoglossal nerve stimulation and maxillomandibular advancement, are invasive and can be, irreversible, expensive, and only suitable for a narrow range of patient types. Legacy dental products, 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.

ProSomnus therapy is covered by most private insurance payers, Medicare, and by 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 insurance, 25% are covered by Medicare and the remaining 5% are paid out of pocket by the patient.

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 dentists an attractive ratio of revenue per chair time in comparison to other dental procedures.

We market and sell our precision intraoral devices to sleep medicine providers in the United States and in select countries around the world through a direct sales force. We currently have 36 direct sales representatives in the United States, Canada, and Europe. Our 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 generated revenue of $27.7 million, with a net loss of $24.1 million, for the year ended December 31, 2023, compared to revenue of $19.4 million, with a net loss of $7.1 million, for the year ended December 31, 2022.

Macroeconomic Environment

Uncertainty surrounding macroeconomic and geopolitical factors in the U.S. and globally characterized by the supply chain environment, inflationary pressure, higher interest rates, instability in the global financial markets, labor shortages, significant disruptions in the commodities' markets as a result of the military conflicts in Ukraine and the Middle East, and the introduction of or changes in tariffs or trade barriers may result in a recession, which could have a material adverse effect on our long-term business.

We maintain the majority of our cash and cash equivalents in accounts with major U.S. financial institutions, and our deposits exceed insured limits. Market conditions could impact the viability of these institutions. To date, these market conditions and liquidity concerns have not impacted our results of operations. However, in the event of failure of any of the financial institutions where we maintain our cash and cash equivalents, there can be no assurance that we would be able to access uninsured funds in a timely manner or at all. Any inability to access or delay in accessing these funds could adversely affect our business and financial position.

Recent Financing Transaction

On September 20, 2023, the Company entered into a Securities Purchase Agreement with the Investors. The Investors include certain members of the Company's Board of Directors and certain executive officers of the Company, as well as affiliates and investment vehicles for such persons that held the Company's Existing Convertible Notes. Convertible Noteholders representing approximately $3.4 million in principal amount of the Senior Convertible Notes and approximately $12.1 million in principal amount of the Subordinated Convertible Notes participated in the Financing Transaction.

The Financing Transaction closed on three dates: September 20, 2023, September 26, 2023, and October 20, 2023. The exchange of the Existing Convertible Notes, including the entrance into the indentures governing the New Notes, occurred on October 11, 2023.

In such Exchanges, the Noteholder Investors received a reset of the conversion price of the amount of principal of the existing notes equal to up to 300% of the purchase price paid by such Noteholder Investor to purchase its Series A Preferred Stock. Any proceeds in excess of such amount results in the Noteholder Investors purchasing Transaction Warrants.

As a result of the Financing Transaction, during September and October 2023, the Noteholder Investors effectively invested an aggregate of $7.3 million of cash in the Company in exchange for 7,276 shares of Series A Preferred Stock, Transaction Warrants exercisable into an aggregate of 2,304,524 shares of Common Stock, and the repricing of the conversion feature of their Convertible Notes, while the other Investors contributed an aggregate of $3.2 million of cash to the Company in exchange for 3,150 shares of Series A Preferred Stock and Transaction Warrants exercisable into an aggregate of 3,150,000 shares of Common Stock.

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.

Description of Certain Components of Financial Data

Revenue

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 2 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)

Other income (expense) primarily relates to interest expense as well as the change in fair value of our convertible debt, earnout liability, warrants classified as liabilities, losses on the extinguishment of debt, and other financing costs.

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 bases of assets and liabilities, and the enacted tax rates in effect in future periods. The Company recorded a full valuation allowance as of December 31, 2023 and December 31, 2022. 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 consolidated statements of operations.

Results of Operations

Comparison of the Fiscal Years ended December 31, 2023 and 2022 ($ in thousands):

	Year Ended December 31,		Change	
	2023	2022	$	%
Revenue	$ 27,652	$ 19,393	$ 8,259	42.6 %
Operating expenses:				
Cost of revenue	13,641	9,127	4,514	49.5 %
Sales and marketing	13,085	8,865	4,220	47.6 %
General and administrative	15,230	9,895	5,335	53.9 %
Research and development	4,802	2,981	1,821	61.1 %
Total operating expenses	46,758	30,868	15,890	51.5 %
Other income (expense)				
Interest expense, net	(5,382)	(6,120)	738	(12.1)%
Change in fair value of earnout liability	12,190	9,260	2,930	n/m
Change in fair value of debt	1,328	553	775	n/m
Change in fair value of warrant liability	1,896	3,237	(1,341)	n/m
Loss on extinguishment of debt	(10,450)	(2,598)	(7,852)	n/m
Other financing expense	(2,473)	—	(2,473)	n/m
Other expense, net	(2,098)	(2)	(2,096)	n/m
Total other income (expense), net	(4,989)	4,330	(9,319)	(215.2)%
Net loss and comprehensive loss	$ (24,095)	$ (7,145)	$ (16,950)	237.2 %

(n/m = not meaningful)

Revenues increased by $8.3 million, or 42.6%, for the year ended December 31, 2023, compared to the year ended December 31, 2022. 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 EVO Product, all of which contributed to increased unit volumes.

Revenue from the Company's largest customer was 3% for the year ended December 31, 2023, and 5.7% for the year ended December 31, 2022.

Total cost of revenue increased by $4.5 million, or 49.5%, for the year ended December 31, 2023, compared to the year ended December 31, 2022. 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.

Sales and marketing expenses increased by $4.2 million, or 47.6%, for the year ended December 31, 2023, compared to the year ended December 31, 2022. This increase was primarily driven by an increase in personnel and consulting-related expenses of $2.7 million due to expansion of the sales team. Distribution and advertising increased by $0.9 million and sales and marketing events increased $0.3 million, and travel in-person events increased by $0.2 million.

General and administrative expenses increased by $5.3 million, or 53.9%, for the year ended December 31, 2023, compared to the year ended December 31, 2022. This increase was driven primarily by $1.3 million increase in personnel costs and bonuses, $1.4 million increase in professional services, $2.9 million increase in costs that scale with general expenses including credit card fees, recruiting, software, utilities, rent and depreciation, $0.9 million related to legal fees and $0.2 million increase in costs related to investor relations, offset by $1.4 million decrease in stock based compensation.

Research and development expenses increased by $1.8 million, or 61.1%, for the year ended December 31, 2023, compared to the year ended December 31, 2022. This increase was primarily driven by an increase in headcount-related personnel and consulting costs of $1.5 million and $0.3 million increase in other expenses in research and development.

Total other income (expense) changed by $9.3 million, or 215.2%, from income of $4.3 million for the year ended December 31, 2022, to an expense of $5.0 million for the year ended December 31, 2023. The change was primarily due to the Finance Transaction which resulted in a loss on debt extinguishment of $7.8 million, financing costs of $2.5 million, and additional legal transaction costs of $1.4 million. The change was partially offset by lower interest expense of $0.8 million. Remaining changes in other income (expense) were due to changes in the fair values of the earnout liability, debt, and warrant liability.

LIQUIDITY AND CAPITAL RESOURCES

Going Concern and Management's Plans

Our liquidity needs are to fund our ongoing business initiatives. Historically, our sources of cash were primarily the issuance of equity securities and the incurrence of debt and our uses of cash were to fund our operating needs and to service our indebtedness. We expect to use our existing cash to fund our operations. We have incurred recurring losses from operations and recurring negative cash flows from operating activities. We expect operating losses and negative cash flows from operations to continue for the foreseeable future.

Our ability to continue as a going concern depends on our ability to execute on our plans to achieve revenue growth forecast, control operating costs, and obtain additional financing. We have developed a cash flow breakeven plan pursuant to which we expect to maintain positive cash balances and compliance with debt covenants and commitments. We have commenced the implementation of our plan and believe the plan, when fully implemented as planned, will mitigate the liquidity risks identified. However, our operating plan may change as a result of many factors currently unknown and there can be no assurance that the current operating plan or cash flow break-even plan will be achieved in the time frame anticipated by us. Furthermore, there can be no assurance that we will be able to obtain additional financing on terms acceptable to the Company, on a timely basis or at all.

Based on our current level of expenditures and future cash flow projections, we believe having $6.4 million in unrestricted cash and cash equivalents will not be sufficient for the Company to continue operations as a going concern for at least one year from the issuance date of these consolidated financial statements. Additionally, the indentures governing our Convertible Notes contain monthly and quarterly financial covenants. Failure to comply with the covenants or obtain a waiver and extension from the holders of each series of our Convertible Notes could result in an event of default under each of the indentures governing our Convertible Notes and result in an acceleration of the Convertible Notes, which could raise substantial doubt about our ability to continue as a going concern.

ProSomnus has engaged Piper Sandler as financial advisor to assist ProSomnus with a comprehensive review of financing and strategic alternatives. There can be no assurance that this process will result in us pursuing a transaction or that any transaction, if pursued, will be completed on attractive terms or at all. If we are unable to complete a transaction, it may be necessary to seek other alternatives to further reduce costs or restructure the Company. We do not expect to disclose developments with respect to this process unless and until the evaluation of strategic alternatives has been completed or we have concluded that disclosure is appropriate or legally required. For more information, see the risk factor entitled "We have engaged financial and legal advisors to identify and evaluate possible financial and strategic alternatives and their implications for ProSomnus."

The following table summarizes our cash flows for the periods indicated (in thousands):

	Year Ended December 31,	
	2023	**2022**
Net cash used in (provided by):		
Operating activities	$ (16,127)	$ (10,239)
Investing activities	(1,467)	(1,354)
Financing activities	8,741	26,009
Net change in cash and cash equivalents	$ (8,853)	$ 14,416

Net cash used in operating activities

For the year ended December 31, 2023, net cash used in operating activities of $16.1 million was $5.9 million higher than in prior year primarily due to increased general and administrative expenses such as professional fees and legal costs relating to being a public company as compared to private company for most of 2022, and to a lesser extent by higher increased spending on sales and marketing and research and development 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.

Net cash used in investing activities

For the year ended December 31, 2023 and 2022, net cash used in investing activities of $1.5 million and $1.4 million, respectively, was primarily due to purchases of property and equipment.

Net cash provided by financing activities

For the year ended December 31, 2023, net cash provided by financing activities of $8.7 million was primarily due to the Financing Transaction which resulted in cash proceeds of $10.4 million. Financing cash inflows were partially offset by principal payments under finance lease and equipment financing obligations of $1.4 million, and payment of debt financing cost and taxes related to net share settlement of equity awards totaling $0.3 million.

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.

Contractual Obligations

Below is a summary of short-term and long-term anticipated cash requirements under contractual obligations existing as of December 31, 2023 (in thousands).

	2024	After 2024	Total
Recorded contractual obligations:			
Senior Convertible Notes	$ 848	$ 16,112	$ 16,960
Subordinated Convertible Notes	—	19,834	19,834
Other*	2,192	10,031	12,223
Total	$ 3,040	$ 45,977	$ 49,017

** Represents finance and operating lease liabilities, equipment financing obligations*

During June 2023, we entered into the First Supplemental Indenture (the "Senior Supplemental Indenture") to that certain Indenture, dated December 6, 2022, by and among the Company, ProSomnus Holdings, Inc. and ProSomnus Sleep Technologies, Inc., as guarantors, and Wilmington Trust, National Association, as trustee and collateral agent (as amended, the "Senior Indenture"), pursuant to which the Company issued its Senior Secured Convertible Notes due December 6, 2025 (the "Senior Convertible Notes"). The Senior Supplemental Indenture amends the Senior Indenture to, among other things, (i) make certain changes to the minimum EBITDA and minimum revenue financial covenants in the Senior Indenture, (ii) require mandatory redemption of the Senior Convertible Notes (as described below) and (iii) make certain other revisions as more fully set forth therein. Pursuant to the Senior Indenture, as amended, the Company shall redeem the Senior Convertible Notes in consecutive quarterly installments equal to $847,990 in the aggregate on January 1, April 1, July 1 and October 1 of each year, commencing October 1, 2024, until the earlier of the maturity date of the Senior Convertible Notes or the date the Senior Convertible Notes are no longer outstanding.

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 consolidated financial statements and the reported amounts of revenue and expenses during the reporting period.

While our significant accounting policies are also described in Note 2 - Summary of Significant Accounting Policies of our notes to our consolidated financial statements appearing elsewhere in this report, we believe the following accounting policies require the most significant judgment in the preparation of our consolidated financial statements. The critical accounting estimates should be read in conjunction with our risk factors as disclosed in "Item 1A. Risk Factors."

Fair Value of Financial Instruments

Critical accounting estimates to our consolidated financial statements include the fair value of our convertible notes and the fair value of our earnout liability as well as one-time fair value measurements of the Series A Preferred Stock and Transaction Warrants issued in connection with our recent Financing Transaction. Fair value is defined as the price that would be received for sale of an asset or paid for transfer of a liability, in an orderly transaction between market participants at the measurement date. GAAP establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to unobservable inputs (Level 3 measurements). These tiers include:

- Level 1, defined as observable inputs such as quoted prices (unadjusted) for identical instruments in active markets;
- Level 2, defined as inputs other than quoted prices in active markets that are either directly or indirectly observable such as quoted prices for similar instruments in active markets or quoted prices for identical or similar instruments in markets that are not active; and
- Level 3, defined as unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions, such as valuations derived from valuation techniques in which one or more significant inputs or significant value drivers are unobservable.

In some circumstances, the inputs used to measure fair value might be categorized within different levels of the fair value hierarchy. In those instances, the fair value measurement is categorized in its entirety in the fair value hierarchy based on the lowest level input that is significant to the fair value measurement.

Senior and Subordinated Convertible Notes

We account for our Senior Convertible Notes and Subordinated Convertible Notes at fair value on a recurring basis. Changes in fair value are recognized as non-operating gain or loss in the consolidated statements of operations (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 estimated fair value of our convertible notes is determined using a Monte Carlo Simulation method. We simulate the stock price using a Geometric Brownian Motion until maturity. For each simulation path, we calculate 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 significant assumptions used in the valuation include the risky yield (risk-adjusted discount rate) and volatility rate.

Earnout Liability

Our earnout liability is valued using a Monte-Carlo simulation in order to simulate the future path of our stock price over the earnout period. The carrying amount of the liability may fluctuate significantly and actual amounts paid may be materially different from the liability's estimate value. The significant assumptions used in the valuation include the Company's stock price, volatility and the drift rate.

Fair value measurements related to Financing Transaction

During September and October 2023, the Noteholder Investors effectively invested an aggregate of $7.3 million of cash in the Company in exchange for 7,276 shares of Series A Preferred Stock, Transaction Warrants exercisable into an aggregate of 2,304,524 shares of Common Stock, and the repricing of the conversion feature of their Convertible Notes, while the other Investors contributed an aggregate of $3.2 million of cash to the Company in exchange for 3,150 shares of Series A Preferred Stock and Transaction Warrants exercisable into an aggregate of 3,150,000 shares of Common Stock. The one-time fair value measurements of the Series A Preferred Stock and Transaction Warrants in connection with the transaction were determined by the Company with assistance of a third-party valuation specialist and include Level 3 fair value inputs. The significant assumptions used related to the Series A Preferred Stock include a risky yield (risk-adjusted discount rate) of 42.0%, volatility rate of 65.0%, risk free rate of 5.0%, and an estimated exit date of April 2026. The assumptions used related to the Transaction Warrants include an asset price of $0.97, volatility rate of 65.0%, risk free rate of 4.5%, no dividends, and an expected term of 5.0 years.

Allowance for Credit Losses

We adopted ASU 2016-13, Financial Instruments-Credit Losses (Topic 326), The provision sets forth a "current expected credit loss" model which requires us to measure all expected credit losses for financial instruments held at the reporting date based on historical experience, current conditions, and reasonable supportable forecasts. This replaces the prior incurred loss model and is applicable to the measurement of credit losses on financial assets measured at amortized cost and applies to accounts receivables. We adopted this standard as of January 1, 2023, with no impact. See also Note 2 to the audited consolidated financial statements for further discussion of our adoption of ASU 2016-13.

Emerging Growth Company and Smaller Reporting Company Status

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 stockholder 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.

Additionally, we are a "smaller reporting company" as defined in Item 10(f)(1) of Regulation S-K. Smaller reporting companies may take advantage of certain reduced disclosure obligations, including, among other things, providing only two years of audited financial statements. We will remain a smaller reporting company until the last day of the fiscal year in which (i) the market value of our ordinary shares held by non-affiliates exceeds $250 million as of the prior June 30 or (ii) our annual revenue exceeded $100 million during such completed fiscal year and the market value of our ordinary shares held by non-affiliates exceeds $700 million as of the prior June 30.

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 and restricted cash as of December 31, 2023 consisted of $6.4 million and $0.7 million, respectively, held 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.

Our Subordinated Convertible Notes bear variable interest rate at 8.5% on December 28, 2023 plus an additional 9% per annum. As a result, as interest rates increase, our interest expense increases. The interest on our Subordinated Convertible Notes is paid-in-kind quarterly; therefore, increasing interest rates result in increases in the outstanding balance of the Subordinated Convertible Notes.

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 Stockholders and Board of Directors of ProSomnus, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of ProSomnus, Inc. (the "Company") as of December 31, 2023 and 2022, the related consolidated statements of operations, redeemable convertible preferred stock and stockholders' deficit, and cash flows for each of the two years in the period ended December 31, 2023, 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, 2023 and 2022, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2023, in conformity with accounting principles generally accepted in the United States of America.

Explanatory Paragraph – Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 2, the Company has incurred significant losses and needs to raise additional funds to meet its obligations and sustain its operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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 audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

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

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

/s/ Marcum LLP

Marcum LLP

We have served as the Company's auditor since 2022.

Portland, Maine
March 27, 2024

PCAOB ID Number 688

PROSOMNUS, INC.
CONSOLIDATED BALANCE SHEETS
(*In thousands, except share amounts and par value*)

	December 31, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 6,363	$ 15,916
Restricted cash	700	—
Accounts receivable, net	3,839	2,843
Inventory	2,039	640
Prepaid expenses and other current assets	1,369	1,851
Total current assets	14,310	21,250
Property and equipment, net	3,358	2,404
Finance lease right-of-use assets	3,265	3,650
Operating lease right-of-use assets	5,069	5,633
Other assets	285	263
Total assets	$ 26,287	$ 33,200
LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 4,047	$ 2,102
Accrued expenses and other current liabilities	6,756	3,706
Equipment financing obligation	57	59
Finance lease liabilities	1,052	1,009
Operating lease liabilities	304	215
Senior Convertible Notes at fair value, current portion	2,125	—
Total current liabilities	14,341	7,091
Equipment financing obligation, net of current portion	129	186
Finance lease liabilities, net of current portion	2,009	2,081
Operating lease liabilities, net of current portion	5,221	5,526
Senior Convertible Notes at fair value, net of current portion	12,152	13,651
Subordinated Convertible Notes at fair value	18,320	10,356
Earnout and warrant liability	716	14,802
Total liabilities	52,888	53,693
Commitments and contingencies		
Redeemable convertible preferred stock:		
Redeemable Convertible Series A Preferred Stock, $0.0001 par value, stated value $1,000; 25,000 shares designated at December 31, 2023; 9,436 shares issued and outstanding at December 31, 2023; liquidation preference of $14,154 at December 31, 2023; No shares authorized, issued or outstanding at December 31, 2022	11,555	—
Stockholders' deficit:		
Preferred stock, $0.0001 par value, 1,475,000 and 1,000,000 shares authorized at December 31, 2023 and December 31, 2022, respectively; no shares issued or outstanding	—	—
Common Stock, $0.0001 par value, 150,000,000 and 100,000,000 shares authorized at December 31, 2023 and December 31, 2022, respectively; 17,388,599 and 16,041,464 shares issued and outstanding at December 31, 2023 and December 31, 2022, respectively	2	2
Additional paid-in capital	196,731	190,299
Accumulated deficit	(234,889)	(210,794)
Total stockholders' deficit	(38,156)	(20,493)
Total liabilities, redeemable convertible preferred stock and stockholders' deficit	$ 26,287	$ 33,200

See accompanying notes to consolidated financial statements.

PROSOMNUS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS
(*In thousands, except per share data*)

	Years Ended December 31,	
	2023	**2022**
Revenue	$ 27,652	$ 19,393
Operating expenses:		
Cost of revenue	13,641	9,127
Sales and marketing	13,085	8,865
General and administrative	15,230	9,895
Research and development	4,802	2,981
Total operating expenses	46,758	30,868
Net loss from operations	(19,106)	(11,475)
Other income (expense)		
Interest expense, net	(5,382)	(6,120)
Change in fair value of earnout liability	12,190	9,260
Change in fair value of debt	1,328	553
Change in fair value of warrant liability	1,896	3,237
Loss on debt extinguishment	(10,450)	(2,598)
Other financing expense	(2,473)	—
Other expense, net	(2,098)	(2)
Total other income (expense), net	(4,989)	4,330
Net loss and comprehensive loss	$ (24,095)	$ (7,145)
Net loss per share attributable to Common Stockholders, basic and diluted	$ (1.49)	$ (0.71)
Weighted average shares of Common Stock, basic and diluted	16,177	10,022

See accompanying notes to consolidated financial statements.

PROSOMNUS, INC.

CONSOLIDATED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT
(*In thousands, except share data*)

	Redeemable Convertible Preferred Stock						Additional		
	Series B		Series A		Common Stock		Paid-In	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	Deficit
Balance as of January 1, 2022	**7,288,333**	**$ 12,390**	**26,245**	**$ 26,245**	**24,566,386**	**$ 3**	**$ 150,426**	**$ (203,649)**	**$ (53,220)**
Vesting of stock awards	—	—	—	—	854,507	—	2,157	—	2,157
Issuance of Series A Preferred - Convertible Bridge Notes	—	—	13,081	—	—	—	13,081	—	13,081
Issuance of Series A Preferred - ProSomnus Common Holders	—	—	5,945	—	—	—	—	—	—
Issuance of Series B Preferred - Stock for Warrants	161,112	—	—	—	—	—	580	—	580
Merger Recapitalization - Preferred	(7,449,445)	(12,390)	(45,271)	(26,245)	7,208,865	1	38,636	—	38,637
Merger Recapitalization - Common	—	—	—	—	(21,336,475)	(2)	—	—	(2)
Issuance of Common Stock - Services	—	—	—	—	716,223	—	7,159	—	7,159
Issuance costs - ProSomnus Inc.	—	—	—	—	—	—	(12,641)	—	(12,641)
Conversion of LAAA Founder Common Stock	—	—	—	—	1,054,390	—	—	—	—
Issuance of Common Stock - Lakeshore Public Stockholders	—	—	—	—	820,722	—	—	—	—
Issuance of Common Stock - PIPE Equity	—	—	—	—	1,830,133	—	10,250	—	10,250
Issuance of Common Stock - PIPE Debt SPA Shares	—	—	—	—	326,713	—	479	—	479
Assumption of SPAC Assets and Liabilities	—	—	—	—	—	—	2,242	—	2,242
Earn-out liability	—	—	—	—	—	—	(22,070)	—	(22,070)
Net loss	—	—	—	—	—	—	—	(7,145)	(7,145)
Balance as of December 31, 2022	**—**	**—**	**—**	**—**	**16,041,464**	**2**	**190,299**	**(210,794)**	**(20,493)**
Issuance of shares, net	—	—	—	—	16,166	—	136	—	136
Conversion of Subordinated Convertible Notes	—	—	—	—	230,494	—	920	—	920
Issuance of Series A Preferred Stock	—	—	10,426	12,767	—	—	—	—	—
Issuance of Common Stock warrants	—	—	—	—	—	—	3,057	—	3,057
Conversion of Series A Preferred Stock to Common Stock	—	—	(990)	(1,212)	990,000	—	1,212	—	1,212
Vesting of restricted stock units	—	—	—	—	192,500	—	—	—	—
Taxes paid related to net share settlement of equity awards	—	—	—	—	(82,025)	—	(70)	—	(70)
Stock-based compensation expense	—	—	—	—	—	—	1,177	—	1,177
Net loss	—	—	—	—	—	—	—	(24,095)	(24,095)
Balance as of December 31, 2023	**—**	**$ —**	**9,436**	**$ 11,555**	**17,388,599**	**$ 2**	**$ 196,731**	**$ (234,889)**	**$ (38,156)**

See accompanying notes to consolidated financial statements.

PROSOMNUS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS
(*In thousands*)

	Years Ended December 31,	
	2023	**2022**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (24,095)	$ (7,145)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	978	424
Reduction of finance right-of-use asset	952	773
Reduction of operating right-of-use asset	291	207
Noncash interest	3,377	5,004
Amortization of debt financing costs	1,468	145
Allowance for credit losses	120	139
Stock-based compensation	1,177	2,157
Change in fair value of earnout liability	(12,190)	(9,260)
Change in fair value of debt	(1,328)	(553)
Change in fair value of warrant liability	(1,896)	(3,237)
Loss on debt extinguishment	10,450	2,598
Loss on financing transactions	2,473	—
Loss on disposal of property and equipment	117	—
Right-of-use asset impairment	273	—
Shares issued for services received, net	136	—
Other non-cash operating expense	124	2
Changes in operating assets and liabilities:		
Accounts receivable	(1,116)	(883)
Inventory	(1,399)	(261)
Prepaid expenses and other current assets	482	(1,745)
Other assets	(22)	(108)
Accounts payable	974	1,146
Accrued expenses and other current liabilities	2,743	517
Operating lease liabilities	(216)	(159)
Net cash used in operating activities	**(16,127)**	**(10,239)**
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	(1,467)	(1,354)
Net cash used in investing activities	**(1,467)**	**(1,354)**
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from PIPE Equity Financing	—	9,450
Proceeds from SPAC Trust	—	4,921
Issuance costs paid in closings	—	(8,243)
Proceeds from Issuance of Convertible Notes	—	27,452
Proceeds from line of credit	—	24,362
Repayments of line of credit	—	(24,950)
Proceeds from issuance of subordinated notes	—	375
Repayments of subordinated notes	—	(75)
Principal payments on finance lease obligations	(1,303)	(1,222)
Principal payments on equipment financing obligation	(59)	(56)
Proceeds from issuance of Series A Preferred Stock and warrants	10,426	—
Repayments of subordinated loan and security agreement	—	(10,652)
Proceeds from issuance of unsecured subordinated promissory notes	—	5,261
Payment of debt financing costs	(253)	—
Repayments of unsecured subordinated promissory notes	—	(614)
Taxes paid related to net share settlement of equity awards	(70)	—
Net cash provided by financing activities	**8,741**	**26,009**
Net change in cash, cash equivalents, and restricted cash	(8,853)	14,416
Cash, cash equivalents, and restricted cash at beginning of year	15,916	1,500
Cash, cash equivalents, and restricted cash at end of year	$ 7,063	$ 15,916

See accompanying notes to consolidated financial statements.

PROSOMNUS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS (Continued)
(*In thousands*)

	Years Ended December 31,	
	2023	**2022**
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 1,602	$ 1,189
Supplemental disclosure of noncash investing and financing activities:		
ROU assets obtained in exchange for finance lease obligations	$ 1,274	$ 2,234
ROU assets obtained in exchange for operating lease obligations	$ —	$ 5,436
Addition of ROU assets from finance lease modification	$ —	$ 239
Conversion of Subordinated Convertible Notes to Common Stock	$ 920	$ —
Conversion of Series A Preferred Stock to Common Stock	$ 1,212	$ —
Conversion of Bridge Notes into Equity	$ —	$ 13,081
Issuance of stock for repayment of Subordinated Loan and Security agreement and Bridge Loan (secured subordinated loan)	$ —	$ 800
Issuance of Subordinated Convertible Notes for repayment of Subordinated Loan and Security agreement and Bridge Loan (secured subordinated loan)	$ —	$ 2,548
Issuance of Common stock warrants in connection with Senior and Subordinated Convertible Notes	$ —	$ 1,992
Issuance of Common stock in exchange for investment banking services	$ —	$ 7,159

See accompanying notes to consolidated financial statements.

PROSOMNUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1 — DESCRIPTION OF THE BUSINESS

Company Organization

ProSomnus, Inc., and its wholly owned subsidiaries, ProSomnus Holdings, Inc. and 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, ProSomnus 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 PRESENTATION AND SUMMARY OF 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").

Certain prior year balances have been reclassified in order to conform to the current period presentation. These reclassifications had no impact on the Company's previously reported statement of financial condition, operating results or cash flows.

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All 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. The Company expects operating losses and negative cash flows from operations to continue for the foreseeable future.

In accordance with Financial Accounting Standards Board (the "FASB") Accounting Standards Update ("ASU") ASU 2014-15, *Presentation of Financial Statements—Going Concern (Subtopic 205-40) ("ASC 205-40")*, the Company has the responsibility to evaluate whether conditions and/or events raise substantial doubt about its ability to meet its future financial obligations as they become due within one year after the date that the financial statements are issued. This evaluation requires management to perform two steps. First, management must evaluate whether there are conditions and events that raise substantial doubt about the entity's ability to continue as a going concern. Second, if management concludes that substantial doubt is raised, management is required to consider whether it has plans in place to alleviate that doubt. Disclosures in the notes to the consolidated financial statements are required if management concludes that substantial doubt exists or that its plans alleviate the substantial doubt that was raised.

The accompanying consolidated financial statements have been prepared in accordance with U.S. GAAP assuming that the Company will continue as a going concern. The financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result should the Company be unable to continue as a going concern.

Management's Plans Related to Going Concern

The Company's ability to continue as a going concern depends on its ability to execute on its plans to achieve revenue growth forecast, control operating costs, and obtain additional financing. The Company has developed a cash flow breakeven plan pursuant to which the Company expects to maintain positive cash balances and compliance with its debt covenants and commitments. The Company has commenced the implementation of its plan and believes the plan, when fully implemented as planned, will mitigate the liquidity risks identified. However, the Company's operating plan may change as a result of many factors currently unknown and there can be no assurance that the current operating plan or cash flow break-even plan will be achieved in the time frame anticipated by the Company.

Based on current level of expenditures and future cash flow projections, the Company believes having $6.4 million in unrestricted cash and cash equivalents will not be sufficient for the Company to continue operations as a going concern for at least one year from the issuance date of these consolidated financial statements. Additionally, the indentures governing our Convertible Notes contain monthly and quarterly financial covenants. Failure to comply with the covenants or obtain a waiver and extension from the holders of each series of our Convertible Notes could result in an event of default under each of the indentures governing our Convertible Notes and result in an acceleration of the Convertible Notes. The Company believes these factors raise substantial doubt about its ability to continue as a going concern.

Use of Estimates

The preparation of consolidated financial statements in conformity with 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. Though macroeconomic factors such as inflation, exchange rate fluctuations and concerns about an economic downturn present additional uncertainty, the Company continues to use the best information available to form its critical accounting estimates. Actual results could differ from these estimates, and such differences could materially affect the results of operations reported in future periods. The Company's significant estimates in these consolidated financial statements relate to the fair values, and the underlying assumptions used to formulate such fair values, of its Series A Preferred Stock, Convertible Notes, earn-out liability, and warrants. Estimates also include the provision for credit losses, warranty and earned discount accruals, measurements of tax assets and liabilities and stock-based compensation.

Concentrations, Credit Risk and Market 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, 2023 and 2022.

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"). As of December 31, 2023 and 2022, the Company had $6.8 million and $15.7 million in excess of the FDIC insured limit, respectively. The Company's investment policy, which is predicated on capital preservation and liquidity, limits investments to instruments denominated and payable in US dollars. The Company believes its credit risk is mitigated due to the high quality of the banks in which it places its deposits. Historically, the Company has not experienced significant credit losses from financial instruments.

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.

The carrying amounts of financial instruments such as cash and cash equivalents, restricted cash, accounts receivable, prepaid expenses and other current assets, accounts payable, and accrued expenses approximate the related fair values due to the short-term maturities of these instruments. The carrying value of the Company's equipment financing obligation is considered to approximate its fair value because the interest rate is comparable to current rates for financing available to the Company. Under the fair value option as prescribed by FASB Accounting Standards Codification ("ASC") 825, *Financial Instruments*, The Company has elected to record the Company's convertible debt instruments at fair value. The Company's earnout and warrant liabilities are presented at fair value on the consolidated balance sheets.

The following tables provide a summary of the Company's financial instruments that are measured at fair value on a recurring basis:

	December 31, 2023			
	Fair Value	Level 1	Level 2	Level 3
Senior Convertible Notes	$ 14,277	$ —	$ —	$ 14,277
Subordinated Convertible Notes	18,320	—	—	18,320
Earnout liability	620	—	—	620
Warrant liability	96	—	—	96

	December 31, 2022			
	Fair Value	Level 1	Level 2	Level 3
Senior Convertible Notes	$ 13,651	$ —	$ —	$ 13,651
Subordinated Convertible Notes	10,356	—	—	10,356
Earnout liability	12,810	—	—	12,810
Warrant liability	1,992	—	—	1,992

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.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less when purchased to be cash and cash equivalents. At December 31, 2023 and 2022, the Company had no cash equivalents.

Restricted Cash

The Company's restricted cash as of December 31, 2023 of $0.7 million consisted of a letter of credit on hand with the Company's financial institution as collateral for an office lease.

Accounts Receivable and Allowance for Credit Losses

Accounts receivable are stated at the amount the Company expects to collect. The Company maintains allowances for credit losses for estimated losses resulting from the inability of its customers to make required payments. The Company has not historically assessed finance charges on past due accounts, but retains the right to do so. Receivables are considered past due based on the contractual payment terms. The Company reserves a percentage of trade receivable balance based on collection history and current economic trends that the Company expects will impact the level of credit losses over the life of the receivables. These reserves are re-evaluated on a regular basis and adjusted, as needed. Once a receivable is deemed to be uncollectible, such balance is charged against the reserve. The allowance for credit losses amounted to $0.2 million as of both December 31, 2023 and 2022. 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 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. When property and equipment are retired, sold, or otherwise disposed of, the asset's carrying amount and related accumulated depreciation are removed from the accounts and any gain or loss is included in operations.

Impairment of Long-Lived Assets

The Company’s long-lived assets primarily include property and equipment and finance and operating right-of-use assets. The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may 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. During 2023, the Company moved to its new headquarters and principal manufacturing facility. Upon moving, the Company expensed a total of $0.3 million relating to the carrying value of the remaining leasehold improvements and amounts due under the remaining lease term of the previous facility. The right-of-use asset and leasehold improvements charge was recorded in other expense, net in the consolidated statements of operations. There were no impairments of long-lived assets for the year ended December 31, 2022.

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 ("ROU") asset and a lease liability for all leases, except short term leases with an original term of twelve months or less. The ROU 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 ROU asset is initially measured at cost, which primarily comprises the initial amount of the lease liability, less any lease incentives received. All ROU 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.

Senior and Subordinated Convertible Notes

The Company accounts for its Senior Convertible Notes and Subordinated Convertible Notes (as defined below and collectively the "Convertible Notes"), as derivatives in accordance with, ASC 815, *Derivatives and Hedging*, 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.

The Company has analyzed the redemption, conversion, settlement, and other derivative instrument features of its Convertible Notes.

- 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. 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 statements 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 statements 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, the fair value election is allowable provided the debt was not issued at a substantial premium. The Company concluded that the 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 statements of operations as a fair value adjustment of the convertible debt at 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 elected to separately present interest expense related to the Convertible Notes within the consolidated statements of operations. Thus, the multiple embedded derivatives do not need to be separately bifurcated and fair valued. The Convertible Notes are reflected at their respective fair values on the consolidated balance sheets.

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 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 , par value $0.0001 ("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 liability classified warrants are recognized as other income or expense in the consolidated statements of operations.

Warranty

The Company offers an assurance-type warranty guaranteeing the fit and finish of its intraoral devices for three years from the date of initial sale. The accrual for warranty claims totaled $0.5 million and $0.3 million at December 31, 2023 and 2022, respectively, and these amounts are recorded in accrued expenses on the consolidated balance sheets. The Company recognized the related warranty cost as a reduction in revenue.

Revenue Recognition

The Company creates customized precision milled intraoral medical devices and recognizes revenue upon meeting the following criteria:

- Identifying the contract with a customer: Customers submit an order in the form of a prescription and oral scan to the Company.
- Identifying the performance obligations within the contract: The sole performance obligation is the delivery of a completed customized intraoral device.
- Determining the transaction price: Prices are determined by standardized pricing sheets and adjusted for discounts, allowances, and remakes.
- Allocating the transaction price to the performance obligations: The full transaction price is allocated to 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. The Company charges 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. The Company does not have a financing component related to its revenue arrangements.

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. Accordingly, the Company expenses employee sales commissions when incurred as the period over which the sales commission asset that would have been recognized is less than one year.

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 manufacturing overhead costs.

Research and Development

Research and development costs are charged to operating expense as incurred.

Advertising

Advertising costs are expensed as incurred and totaled $0.1 million for both the years ended December 31, 2023 and 2022.

Stock-Based Compensation

The Company measures stock-based awards, including stock options and restricted stock units (RSUs) granted to employees, directors, and non-employee service providers based on the estimated fair values of the awards on the date of the grant. Stock-based compensation expense for awards with service-based vesting is recognized on a straight-line basis over the requisite service period, which is generally the vesting period of such awards, as a component of operating expenses within the consolidated statements of operations. For awards that include performance conditions stock-based compensation expense is recognized on a graded vesting basis over the requisite service period. Compensation expense is not recognized until the performance condition becomes probable. The Company accounts for forfeitures related to awards as they occur.

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model. This valuation model for stock-based compensation expense requires the Company to make assumptions and judgments about the variables used in the calculation including the expected term, the volatility of the Company's Common Stock, and an assumed risk-free interest rate. As a result, if the Company revises its assumptions and estimates, the Company's stock-based compensation expense could change.

The grant date fair value of RSUs is measured as the fair value per share of the Company's Common Stock on the date of grant.

Income Taxes

The Company accounts for income taxes under an asset and liability methodology. 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.

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.

Recently adopted accounting pronouncements

During June 2016, the FASB issued ASU 2016-13 - *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* (ASU 2016-13) which significantly changed how entities measure credit losses for most financial assets and certain other instruments that aren't measured at fair value through net income. The most significant change in this standard is a shift from the incurred loss model to the expected loss model. Under the standard, disclosures are required to provide users of the financial statements with useful information in analyzing an entity's exposure to credit risk and the measurement of credit losses. Financial assets held by the Company that are subject to the guidance in ASU 2016-13 are accounts receivable. The Company adopted ASU 2016-13 effective January 1, 2023. The impact of the adoption was not considered material to the consolidated financial statements and primarily resulted in new and enhanced disclosures only.

During August 2020, the FASB issued *ASU 2020-06, Debt-Debt with Conversion and Other Options (Subtopic 470-20)* and *Derivatives and Hedging- Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*, to clarify the accounting for certain financial instruments with characteristics of liabilities and equity. The amendments in this update reduce the number of accounting models for convertible debt instruments and convertible preferred stock by removing the cash conversion model and the beneficial conversion feature model. Limiting the accounting models will result in fewer embedded conversion features being separately recognized from the host contract. Convertible instruments that continue to be subject to separation models are (1) those with embedded conversion features that are not clearly and closely related to the host contract, that meet the definition of a derivative, and that do not qualify for a scope exception from derivative accounting and (2) convertible debt instruments issued with substantial premiums for which the premiums are recorded as paid-in-capital. In addition, this ASU improves disclosure requirements for convertible instruments and earnings-per-share guidance. The ASU also revises the derivative scope exception guidance to reduce form-over-substance-based accounting conclusions driven by remote contingent events. The Company adopted ASU 2020-06 effective January 1, 2023, which eliminated the need to assess whether a beneficial conversion feature needs to be recognized upon the issuance of new convertible instruments. The adoption of the standard did not have a material impact on the Company's consolidated financial statements.

Recent Accounting Pronouncements not Yet Adopted

During June 2022, the FASB issued ASU 2022-03, *Fair Value Measurement of Equity Securities Subject to Contractual Sale Restrictions*. The amendments in this update provide that a contractual restriction on the sale of an equity security is not considered part of the unit of account of the equity security and, therefore, is not considered in measuring fair value. The amendments in this update also require additional disclosures for equity securities subject to contractual sales restrictions. ASU 2022-03 is effective for years beginning after December 15, 2023, though early adoption is permitted. The Company is currently evaluating the impact of this standard on the Company's consolidated financial statements and related disclosures.

During October 2023, the FASB issued ASU 2023-06, *Disclosure Improvements: Codification Amendments in Response to the SEC's Disclosure Update and Simplification Initiative*. The FASB issued the standard to introduce changes to US GAAP that originate in either SEC Regulation S-X or S-K, which are rules about the form and content of financial reports. The provisions of the standard are contingent when the SEC removes the related disclosure provisions from Regulation S-X and S-K. The Company does not expect the provisions of the standard to have a material impact on the Company's consolidated financial statements and related disclosures.

During November 2023, the FASB issued ASU 2023-07, *Segment Reporting—Improvements to Reportable Segment Disclosures*. The new FASB guidance requires incremental disclosures related to a public entity's reportable segments but does not change the definition of a segment, the method for determining segments, or the criteria for aggregating operating segments into reportable segments. The FASB issued the new guidance primarily to provide financial statements users with more disaggregated expense information about a public entity's reportable segments. The ASU is effective for public entities for fiscal years beginning after December 15, 2023, and interim periods in fiscal years beginning after December 15, 2024. The guidance is effective for the Company's 2024 Form 10-K. The ASU should be adopted retrospectively unless it is impracticable to do so. Upon adoption, a public entity will adopt the ASU as of the beginning of the earliest period presented. However, the significant segment expense categories are based on those identified in the current period of adoption, regardless of how expenses may have been reported to the CODM in the prior periods. Entities with a single reportable segment are required to provide all disclosures mandated by the ASU and all existing segment disclosures in ASU Topic 280 *Segment Reporting*. The Company is currently evaluating the impact of adoption on the Company's consolidated financial statements and its related disclosures.

During December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*. ASU 2023-09 is intended to enhance the transparency and decision usefulness of income tax disclosures. The amendments in ASU 2023-09 address investor requests for enhanced income tax information primarily through changes to the rate reconciliation and income taxes paid information. Early adoption is permitted. A public entity should apply the amendments in ASU 2023-09 prospectively to all annual periods beginning after December 15, 2024. The Company does not believe this guidance will have a material impact on the Company's consolidated financial statements.

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 0.5 million public shares of Common Stock of Lakeshore, and issuing an aggregate of $17.0 million principal value Senior secured Convertible Notes and an aggregate of $17.5 million principal value Subordinated secured 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 $113.0 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 $10.24 per share, for an aggregate payment from Lakeshore's trust account of approximately $24.4 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, ("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 Lakeshore founder shares, and private and public warrant holders, as a result of the Business Combination, see Note 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 1,000,000 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;

- 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

- 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 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 $2.6 million elected to convert, immediately prior to the Acquisition Merger. The remaining $0.1 million 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 $6.5 million (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 $2.0 million 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 $0.1 million 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 $2.0 million 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 $0.8 million 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 $2.5 million 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 $9.7 million 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 was converted into 1,002,869 shares of Common Stock on the date of the Merger Transaction based on proceeds of $10.0 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 $3.1 million, amounting to 3,052 shares of Series A Redeemable Convertible Preferred Stock, this was converted into 305,206 shares of Common Stock; and
- 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, 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, totaling 7,449,445 shares; were converted into 2,623,800 shares and 58,000 shares of ProSomnus's Common Stock, respectively; and
- 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 $10.3 million 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 Lakeshore stockholders 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 $1.6 million 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 Stock 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 $7.2 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 the Company's Common Stock at an exercise price of $11.50 per share, and issued an aggregate of 326,713 shares of the Company's Common Stock.

The Merger was accounted for as a reverse recapitalization in accordance with U.S. GAAP. This determination was 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 U.S. GAAP, ProSomnus is the accounting acquirer and the Business Combination was 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 were stated at historical cost, with no goodwill or other intangible assets recorded. Operations prior to the Business Combination are presented as those of ProSomnus Inc.

In connection with the Merger, the Company raised $45.2 million of proceeds including the contribution of $4.9 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; $10.3 million of gross proceeds in connection with the PIPE Equity financing and $30.0 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 $11.5 million in debt of ProSomnus at closing, with the remaining being deposited in ProSomnus' cash account.

NOTE 4 — INVENTORY

Inventory consisted of the following (in thousands):

	As of December 31,	
	2023	2022
Raw materials	$ 1,967	$ 562
Work-in-process	72	78
	$ 2,039	$ 640

The Company did not have any excess or obsolete inventory reserves as of December 31, 2023 and 2022.

NOTE 5 — PROPERTY AND EQUIPMENT

Property and equipment, net consisted of the following (in thousands):

	As of December 31,	
	2023	2022
Manufacturing equipment	$ 4,042	$ 2,517
Computers and software	1,200	1,608
Leasehold improvements	846	442
Furniture	—	27
	6,088	4,594
Less: accumulated depreciation	(2,730)	(2,190)
Property and equipment, net	$ 3,358	$ 2,404

Depreciation and amortization expense for the years ended December 31, 2023 and 2022 was $1.0 million and $0.4 million, respectively.

NOTE 6 — ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

Accrued expenses consisted of the following (in thousands):

	As of December 31,	
	2023	2022
Compensation related accruals	$ 3,387	$ 2,104
Marketing programs	934	612
Interest	382	110
Warranty	465	269
Professional fees	632	129
Inventory purchases and freight	613	—
Other	343	482
	$ 6,756	$ 3,706

NOTE 7 —LEASES

On May 17, 2022, the Company signed a ten-year lease for the Company's corporate headquarters. The lease commenced on December 15, 2022 and resulted in the recognition of $5.4 million of operating ROU asset and lease liability. The monthly payment is approximately $0.1 million and is subject to stated annual escalations. The Company received five (5) months free rent.

The Company provided a $0.3 million security deposit, which is recorded in other assets on the accompanying consolidated balance sheets. The Company's largest investor initially guaranteed $1.7 million for the lease agreement, followed by a rolling one-year guarantee. The Company replaced the guarantee with a letter of credit of $0.7 million secured by a certificate of a deposit for the same amount that is recorded as restricted cash on the accompanying consolidated balance sheet as of December 31, 2023. On February 28, 2023, the Company vacated its previous corporate office premises with a remaining lease term of approximately ten months. Since there was no new cash inflow generated or expected from the sale or sublease of property and leasehold improvements at the location, the Company recorded an impairment loss on the ROU operating lease assets and leasehold improvements of $0.3 million and $0.1 million, respectively. The Company also accrued liabilities of $0.1 million in anticipation of expected common area maintenance payments on the remainder of the lease. The impairment loss and the accrued expenses are reflected as other expense in the consolidated statements of operations.

The Company's finance leases primarily consist of various machinery, equipment, computer-related equipment, and software used in the manufacture of its product. The Company's finance leases have remaining terms from less than one year to five years.

The components of the Company's lease cost, weighted average lease terms and discount rates are presented in the tables below (in thousands, except lease term and discount rate):

	Years Ended December 31,	
	2023	2022
Operating lease expense:		
Operating lease cost	$ 955	$ 325
Finance lease expense:		
Amortization of assets obtained under finance leases	952	773
Interest on lease liabilities	321	289
Variable lease expense	102	—
Total expense	$ 2,330	$ 1,387

	As of December 31,	
Operating leases:	2023	2022
Weighted average remaining lease term (in years)	9.0	9.6
Weighted average discount rate	10.00 %	10.31 %
Finance leases:		
Weighted average remaining lease term (in years)	3.0	3.5
Weighted average discount rate	10.21 %	11.17 %

	Years Ended December 31,	
	2023	2022
Supplemental cash flow information related to operating leases was as follows (in thousands):		
Operating cash flows from operating leases	$ 558	$ 159
Operating cash flows from finance leases	327	773

ROU assets consisted of the following (in thousands):

	As of December 31,	
	2023	2022
Manufacturing equipment	$ 5,237	$ 4,674
Computers and software	700	700
Leasehold improvements	218	218
Total	6,155	5,592
Less accumulated amortization	(2,890)	(1,942)
ROU assets for finance leases	3,265	3,650
ROU assets for operating leases	5,069	5,633
Total ROU assets	$ 8,334	$ 9,283

At December 31, 2023, the following table presents maturities of the Company's finance and operating lease liabilities (in thousands):

Year ending December 31,	Finance	Operating
2024	$ 1,299	$ 836
2025	1,098	861
2026	794	887
2027	304	914
2028	47	941
Thereafter	—	4,056
Total minimum lease payments	3,542	8,495
Less amount representing interest	(481)	(2,970)
Present value of minimum lease payments	3,061	5,525
Less current portion	(1,052)	(304)
Lease obligations, less current portion	$ 2,009	$ 5,221

NOTE 8 — DEBT

Equipment Financing Obligation

At December 31, 2023, the Company's future principal maturities under the equipment financing obligation are summarized as follows (in thousands):

Year ending December 31,	Amount
2024	$ 57
2025	64
2026	65
Total principal maturities	186
Less: current portion	(57)
Equipment financing obligation, net of current portion	$ 129

Convertible Debt Agreements

Senior Convertible Notes

On December 6, 2022, the Company entered into the Indenture for Senior Secured Convertible Notes due December 6, 2025, dated December 6, 2022 by and among the Company, ProSomnus Holdings and ProSomnus Sleep Technologies, as guarantors, and Wilmington Trust, National Association, as trustee and collateral agent (as amended, the "Senior Indenture"), and issued Senior Secured Convertible Notes, due December 6, 2025 (the "Existing Senior Convertible Notes"), with an aggregate principal amount of $17.0 million, pursuant to the senior securities purchase agreement, dated August 26, 2022. In connection with the closing of the offering of the Existing Senior Convertible Notes, the Company issued 36,469 shares of Common Stock and 169,597 warrants (the "Existing Senior Convertible Notes Warrants") to purchase Common Stock. The Existing Senior Convertible Notes Warrants entitle the note holders to purchase shares of Common Stock, subject to adjustment, at a purchase price per share of $11.50. The debt bears interest at 9% per annum. Interest is payable in cash quarterly.

On June 29, 2023, the Company entered into the First Supplemental Indenture, dated as of June 29, 2023, by and among the Company, ProSomnus Holdings and ProSomnus Sleep Technologies, as guarantors, and Wilmington Trust, National Association (the "First Senior Supplemental Indenture"). The First Senior Supplemental Indenture, among other things, (i) effects certain changes to the minimum EBITDA and minimum revenue financial covenants (ii) requires mandatory redemption of the Existing Senior Convertible Notes in consecutive quarterly installments equal to $0.8 million in the aggregate on January 1, April 1, July 1 and October 1 of each year, commencing October 1, 2024, until the earlier of the maturity date of the Existing Senior Convertible Notes or the date the Existing Senior Convertible Notes are no longer outstanding, and (iii) corrects an error in the definition of Conversion Rate.

On September 20, 2023, the Company entered into the Second Supplemental Indenture (the "Second Senior Supplemental Indenture") to the Senior Indenture, by and among the Company, ProSomnus Holdings and ProSomnus Sleep Technologies, as guarantors, and Wilmington Trust, National Association, as trustee and collateral agent. The Second Senior Supplemental Indenture amends the Senior Indenture to, among other things, permit the sale of the securities underlying the convertible debt (the "Securities") and the Exchanges.

Subordinated Convertible Notes

On December 6, 2022, the Company entered into that certain Indenture for Subordinated Secured Convertible Notes due April 6, 2026, dated December 6, 2022 by and among the Company, ProSomnus Holdings and ProSomnus Sleep Technologies, as guarantors, and Wilmington Trust, National Association, as trustee and collateral agent (as amended, the "Subordinated Indenture"), and issued the Subordinated Secured Convertible Notes due April 6, 2026 ("Existing Subordinated Convertible Notes" and, together with the Existing Senior Convertible Notes, the "Existing Convertible Notes"), with an aggregate principal amount of approximately $17.5 million, pursuant to the previously disclosed Subordinated Securities Purchase Agreement, dated August 26, 2022. In connection with the closing of the offering, the Company issued 290,244 shares of Common Stock and 1,745,310 warrants ("Subordinated Convertible Notes Warrants" and, together with the Senior Convertible Notes Warrants, the "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. Interest is due quarterly in cash or in kind at the option of the Company.

On June 29, 2023, the Company entered into the First Supplemental Indenture, dated as of June 29, 2023, by and among the Company, ProSomnus Holdings and ProSomnus Sleep Technologies, as guarantors, and Wilmington Trust, National Association (the "First Subordinated Supplemental Indenture"), which, among other things, (i) effects certain changes to the minimum EBITDA and minimum revenue financial covenants and (ii) corrects an error in the definition of Conversion Rate.

On June 6, 2023, in accordance with the Subordinated Indenture, the conversion rate of the Subordinated Convertible Notes increased from approximately 86.95665 shares of common stock per $1,000 of the sum of the principal amount of the Subordinated Convertible Notes to approximately 192.3808 shares of common stock per $1,000 of the sum of the principal amount of the Subordinated Convertible Notes.

On September 8, 2023, the Company issued 230,494 shares of Common Stock in connection with a notice of conversion from a holder of the Company's Subordinated Convertible Notes, pursuant to which such holder irrevocably exercised its right to convert $1.0 million principal amount. The Company recorded the fair value of the principal amount and accrued interest converted of $0.9 million as Common Stock and additional paid-in capital.

On September 20, 2023, the Company entered into the Second Supplemental Indenture (the "Second Subordinated Supplemental Indenture") to the Subordinated Indenture, pursuant to which the Company issued the Existing Subordinated Convertible Notes. The Second Subordinated Supplemental Indenture amends the Subordinated Indenture to, among other things, permit the sale of the Securities and the Exchanges.

On December 6, 2023, in accordance with the Subordinated Indenture, the conversion rate of the Subordinated Convertible Notes increased from approximately 192.3808 shares of common stock per $1,000 of the sum of the principal amount of the Subordinated Convertible Notes to approximately 222.22222 shares of common stock per $1,000 of the sum of the principal amount of the Subordinated Convertible Notes.

The Convertible Notes include the following embedded features:

Embedded Feature	Nature	Description
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), plus any liquidated damages and any other amounts due in respect of the Notes redeemable in cash.
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.
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.
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, 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.
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.
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.
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 is 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.

- 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 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. Therefore, 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 statements 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 an embedded derivatives, it was not fair valued separately.
- The ability to pay PIK interest feature is clearly and closely related to the debt, and was 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 statements of operations at each balance sheet date in accordance with ASC 815-15-25.

Financing Transaction

On September 20, 2023, the Company entered into a Securities Purchase Agreement (the "Securities Purchase Agreement", and the transactions contemplated by the Securities Purchase Agreement, the "Financing Transaction") with certain third-party and related party investors (the "Investors"), pursuant to which the Company issued (i) an aggregate of 10,426 shares of the Company's Series A Preferred Stock, par value $0.0001 per share (the "Series A Preferred Stock"), for an aggregate purchase price of $10.4 million at a per share purchase price of $1,000, and (ii) (A) with respect to Investors that held the Existing Convertible Notes, new convertible notes on substantially similar terms to such Noteholder Investor's Existing Convertible Notes other than that such new notes will be convertible into shares of Common Stock, at a conversion price of $1.00 per share subject to the terms and conditions of the applicable new indenture pursuant to which the applicable series of New Notes have been issued by the Company (the "New Notes"), in exchange for such Noteholder Investor's portion of the principal amount outstanding of the Existing Notes (the "Exchanges") pursuant to exchange agreements entered into between the Company and each of the Noteholder Investors (together, the "Exchange Agreements") and/or (B) warrants to purchase shares of Common Stock at an exercise price of $1.00 per share (such warrants, the "Transaction Warrants").

The Investors include certain members of the Company's Board of Directors and certain executive officers of the Company, as well as affiliates and investment vehicles for such persons that held the Company's Existing Convertible Notes. Convertible Noteholders representing approximately $3.4 million in principal amount of the Senior Convertible Notes and approximately $12.1 million in principal amount of the Subordinated Convertible Notes participated in the Financing Transaction.

The Financing Transaction closed on three dates: September 20, 2023, September 26, 2023, and October 20, 2023. The exchange of the Existing Convertible Notes, including the entrance into the indentures governing the New Notes, occurred on October 11, 2023.

In such Exchanges, the Noteholder Investors received a reset of the conversion price of the amount of principal of the existing convertible notes equal to up to 300% of the purchase price paid by such Noteholder Investor to purchase its Series A Preferred Stock. Any proceeds in excess of such amount results in the Noteholder Investors purchasing Transaction Warrants.

As a result of the Financing Transaction, during September and October 2023, the Noteholder Investors effectively invested an aggregate of $7.3 million of cash in the Company in exchange for 7,276 shares of Series A Preferred Stock, Transaction Warrants exercisable into an aggregate of 2,304,524 shares of Common Stock, and the repricing of the conversion feature of their Convertible Notes, while the other Investors contributed an aggregate of $3.2 million of cash to the Company in exchange for 3,150 shares of Series A Preferred Stock and Transaction Warrants exercisable into an aggregate of 3,150,000 shares of Common Stock.

Prior to the Financing Transaction, the Senior Convertible Notes and Subordinated Convertible Notes had conversion rates of $5.50 and $5.20 per share, respectively. The repricing of the Convertible Notes to $1.00 per share made the conversion features of the Convertible Notes substantive again based on the Company's stock price as of the Initial Closing.

The Company assessed the accounting for the Financing Transaction with the Noteholder Investors and concluded that it does not meet the criteria for a troubled debt restructuring or an induced conversion. The Company next considered if the transaction represents a debt modification or extinguishment and concluded the transaction represents a debt extinguishment in accordance with ASC paragraph 470-50-40-10 as both of the following circumstances apply:

a. The transaction resulted in a modification of an embedded conversion option, from which the change in the fair value of the embedded conversion option (calculated as the difference between the fair value of the embedded conversion option immediately before and after the modification or exchange) is at least 10 percent of the carrying amount of the original debt instrument immediately before the modification or exchange.

b. The transaction resulted in a modification or an exchange of debt instruments that adds a substantive conversion option.

Accordingly, the Company accounted for the transaction as an extinguishment of the original debt and the recognition of new debt, which is initially measured at its fair value. The fair value of the new debt is used to determine the debt extinguishment gain or loss to be recognized. The Company assessed the classification of the Transaction Warrants issued in connection with the Financing Transaction and determined that the Transaction Warrants are equity classified. As discussed in Note 11– Preferred Stock, the Company determined that the Series A Preferred Stock is mezzanine classified and therefore should be initially recognized at fair value.

The following table summarizes the computation of the loss on debt extinguishment of $10.5 million recognized during the year ended December 31, 2023 (in thousands):

	Amount
Fair value - Senior Convertible Notes (pre-financing)	$ 2,457
Fair value - Subordinated Convertible Notes (pre-financing)	7,617
	10,074
Less consideration transferred to Noteholder Investors:	
Fees paid to Noteholder Investors	(63)
Fair value of Series A Preferred Stock	(8,910)
Fair value of warrants	(1,292)
Fair value of Senior Convertible Notes (post-financing)	(3,599)
Fair value of Subordinated Convertible Notes (post-financing)	(13,936)
	(27,800)
Plus consideration received from Noteholder Investors:	
Cash	7,276
Loss on Debt Extinguishment:	$ (10,450)

The fair values of the Series A Preferred Stock and Transaction Warrants were determined by the Company with assistance of a third-party valuation specialist and include Level 3 fair value inputs. The significant assumptions used related to the Series A Preferred Stock include a risky yield (risk-adjusted discount rate) of 42.0%, volatility rate of 65.0%, risk free rate of 5.0%, and an estimated exit date of April 2026. The assumptions used related to the Transaction Warrants include an asset price of $0.97, volatility rate of 65.0%, risk free rate of 4.5%, no dividends, and an expected term of 5.0 years.

With respect to the non-Noteholder Investors, the accounting fair value of the consideration transferred was also deemed to be greater than the proceeds received. The Company determined that based on the participation level by third-party investors, the transaction does not represent a deemed dividend. As such, the Company recognized a financing loss of $2.5 million which is included in the consolidated statements of operations. The financing loss is computed as follows (in thousands):

	Amount
Cash proceeds received	$ 3,150
Less: fair value of Series A Preferred Stock	(3,857)
Less: fair value of warrants	(1,766)
Other financing expense	$ (2,473)

The Company incurred $1.5 million of legal and other transaction related costs, of which approximately $0.1 million were deemed to be lender costs and included in the computation of the loss on debt extinguishment. The remaining transaction costs were expensed as other expense in the consolidated statements of operations.

Fair Value Election

The Company has elected to measure the Convertible Notes, including the New Notes, in their entirety at fair value with changes in fair value recognized as non-operating gain or loss in the consolidated statements of operations (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 estimated fair value of the convertible note payable was determined using a Monte Carlo Simulation method. The Company simulated the stock price using a Geometric Brownian Motion until maturity. For each simulation path the Company 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 December 31, 2023 and 2022:

	Monte Carlo Simulation Assumptions			
As of December 31, 2023	**Asset Price**	**Risky Yield**	**Expected Volatility**	**Risk-Free Interest Rate**
Senior Convertible Notes	$ 0.98	25.00 %	65 %	4.27 %
Subordinated Convertible Notes	0.98	34.30 %	55 %	4.17 %

	Monte Carlo Simulation Assumptions			
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 changes in fair values of the Convertible Notes for the years ended December 31, 2023 and 2022 (in thousands):

	Senior Convertible Notes	Subordinated Convertible Notes
Beginning fair value, January 1, 2022	$ —	$ —
Issuance of Convertible Notes	14,536	10,223
Change in fair value of debt	(885)	133
Ending fair value, December 31, 2022	13,651	10,356
Paid-in-kind interest	—	3,377
Change in fair value of debt	(516)	(812)
Conversion of Subordinated Convertible Notes to Common Stock	—	(920)
Increase in fair value of debt in connection with debt extinguishment transaction	1,142	6,319
Ending fair value, December 31, 2023	$ 14,277	$ 18,320

The Convertible Notes are subject to a minimum revenue, cash, and EBITDA financial covenants. From July 1, 2023, the Convertible Notes require the Company to maintain a minimum cash balance of $4.5 million on the first day of each calendar month. As of March 1, 2024, the Company violated the minimum cash covenant. On March 25, 2024, the lenders agreed to (i) waive the minimum cash covenant for the period commencing on March 1, 2024 through and including June 30, 2024 provided that the Company's cash balance remains above $2.5 million during such period; and (ii) waive any default under the indentures resulting from any breach by the Company that may have arisen up to March 1, 2024.

Subordinated Notes

During the year ended December 31, 2022, the Company received advances under unsecured subordinated promissory note agreements for total proceeds of $0.4 million. No issuance costs were incurred in 2022.

During 2022, $0.3 million of these advances were made by the Company's stockholders, directors, and employees, while $0.1 million were made by the Company's customers.

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 incentive 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: (i) interest is received as a cash payment ("Cash Notes") and paid on a quarterly basis. Interest expense totaled $0.2 million (including incentives at closing) for the year ended December 31, 2022, for the Cash Notes, and (ii) interest is accrued and added to the principal balance ("PIK Notes") at the commencement of each new calendar year (January 1). Interest expense totaled $2.3 million (including incentives at closing) for the year ended December 31, 2022, for the PIK Notes.

The Cash and PIK Notes have a prepayment penalty that is calculated on the principal and accrued but unpaid interest. The prepayment penalty rates range between 1% and 3% if prepayment is within 1-3 years from the funding date, and the prepayment rate is 5% upon a change in control event.

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 $3.0 million 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").

During March 2022, $0.5 million 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 $0.2 million 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 $2.6 million 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 aggregate amount due, including interest and Bridge Loan Kickers, was $3.1 million, 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 $3.8 million. 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 $9.5 million. 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 $2.0 million. The loan was 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 $3.9 million. 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.

The effective interest rates on the subordinated loan and security agreement ranged from 25.8% - 27.2% and 25.8% - 26.2% for the year ended December 31, 2022.

During the year ended December 31, 2022, the Company made revenue share payments totaling $1.6 million. The outstanding balances of the subordinated loan and security agreement were paid off as of December 31, 2022.

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 $2.0 million to the Company 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 (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. Interest was due in arrears at December 29, 2022 and at the maturity date. Prepayment of the Convertible Bridge Loan Advance was permitted in increments of $0.1 million at any time, and the prepayment required 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; this amount was paid in full on at the close of the Merger Transaction. Interest expense under the Bridge Loan was $0.1 million 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 $0.2 million in the consolidated statements of operations.

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 the 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 $0.8 million 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 $2.5 million 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 $9.7 million of the Subordinated Loan and Security Agreement in cash at the 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 statements of operations, a loss on debt extinguishment of $2.4 million for the Subordinated Loan and Security agreement and the 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.

NOTE 9 — COMMON STOCK WARRANTS

As of December 31, 2023, the Company has 11,966,611 warrants outstanding. An aggregate of 5,454,524 warrants were issued by the Company with issuance of Series A Preferred Stock in September and October 2023 (See Note 11 –Preferred Stock). An aggregate of 1,914,907 warrants were granted by the Company with the issuance of Senior and Subordinated Convertible Notes in December 2022 (See Note 8 – Debt). Additionally, 4,597,180 warrants were issued to holders of Lakeshore founder shares, and private and public warrant holders, as a result of the Business Combination, as summarized 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 warrants to purchase one share 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 to purchase ProSomnus Common Stock to founders of Lakeshore at substantively identical terms as the Private Placement warrants and the Public warrants (Additional Private Warrants).

The following is a summary of the Company's liability classified and equity classified warrant activity for the years ended December 31, 2023 and 2022:

Liability Classified Warrants	Issuance Period	Outstanding December 31, 2022	Granted	Exercised	Cancelled	Outstanding December 31, 2023	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
		1,914,907	—	—	—	1,914,907	

Equity Classified Warrants	Issuance Period	Outstanding December 31, 2022	Granted	Exercised	Cancelled	Outstanding December 31, 2023	Expiration
Private Warrants	Dec-22	196,256	—	—	—	196,256	Dec-27
Additional Private Warrants	Dec-22	300,685	—	—	—	300,685	Dec-27
Public Warrants	Dec-22	4,100,239	—	—	—	4,100,239	Dec-27
Transaction Warrants	Sep-Oct -23	—	5,454,524	—	—	5,454,524	Sep-28
		4,597,180	5,454,524	—	—	10,051,704	

Liability Classified Warrants	Issuance Period	Outstanding December 31, 2021	Granted	Exercised	Cancelled	Outstanding 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
		—	1,914,907	—	—	1,914,907	

Equity Classified Warrants	Issuance Period	Outstanding December 31, 2021	Granted	Exercised	Cancelled	Outstanding December 31, 2022	Expiration
Private Warrants	Dec-22	—	196,256	—	—	196,256	Dec-27
Additional Private Warrants	Dec-22	—	300,685	—	—	300,685	Dec-27
Public Warrants	Dec-22	—	4,100,239	—	—	4,100,239	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	4,597,180	(322,223)	—	4,597,180	

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.

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 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. 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. Therefore, the Convertible Notes Warrants 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 $5.2 million.

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 31, 2023 and 2022, use Level 3 inputs and are calculated using the Black-Scholes option pricing model with the following assumptions (in thousands):

As of December 31, 2023	Exercise Price	Asset Price	Dividend Yield	Expected Volatility	Risk-Free Interest Rate	Expected Life
Convertible Notes Warrants	$ 11.50	$ 0.98	0 %	65 %	3.90 %	3.93 years

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

The changes in fair value of the outstanding warrants classified as liabilities for the year ended December 31, 2023 and 2022 were as follows (in thousands):

	Convertible Notes Warrants - Senior Debt	Convertible Notes Warrants - Subordinated Debt	2020 preferred Series B warrants
Warrant liability, January 1, 2022	$ —	$ —	$ 562
Fair value of warrants granted	465	4,782	—
Fair value of warrants exercised	—	—	(580)
Change in fair value	(288)	(2,967)	18
Warrant liability, December 31, 2022	177	1,815	—
Change in fair value	(168)	(1,728)	—
Warrant liability, December 31, 2023	$ 9	$ 87	$ —

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 the close of Business Combination, the Company issued an aggregate of 4,597,180 warrants to holders of Lakeshore 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.

Transaction Warrants

On September 20, 2023, the Company entered into a Securities Purchase Agreement with third-party and related party investors. The Company issued Series A Preferred Stock and warrants to purchase Common Stock at an exercise price of $1.00 per share (Transaction Warrants) as part of the Financing Transaction (refer to Note 11 – Preferred Stock). The Company has 5,454,524 Transaction Warrants outstanding as of December 31, 2023, which are exercisable at a price of $1.00 per share of Common Stock, and expire five years from grant date. The likelihood that the holders of the Transaction Warrants will exercise their warrants and the amount of cash proceeds that the Company would receive is dependent upon the market price of the Company's Common Stock, which was below the exercise price for the Transaction Warrants as of December 31, 2023.

ASC 815-10-15-74(a) provides a scope exception from Derivative Accounting 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 Private Warrants, Public Warrants, Additional Private Warrants, and Transaction Warrants meet the derivative scope exception in 815-10-15-74(a) as they 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 the 4,597,180 Private Warrants, Public Warrants, and Additional Private Warrants at issuance was $0.7 million. 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 aggregate fair value of the Transaction Warrants at issuance was $1.3 million. The assumptions used to determine the fair value of the Transaction Warrants included an asset price of $0.97, volatility rate of 65.0%, risk-free rate of 4.5%, no dividends, and an expected term of 5.0 years.

NOTE 10 — COMMON STOCK

As of December 31, 2023 and 2022, the Company had 150,000,000 and 100,000,000 shares of Common Stock authorized for issuance, respectively, with par value of $0.0001. The number of authorized shares was increased from 100,000,000 shares to 150,000,000 shares by the Company's stockholders approval on December 6, 2023, through an amendment to the Amended and Restated Certificate of Incorporation.

The Company has reserved shares of Common Stock for the following:

	As of December 31,	
	2023	**2022**
2022 Equity Incentive Plan reserve	5,889,525	2,411,283
Reserve for earn-out shares	3,000,000	3,000,000
Reserve for exercise of Public Warrants	4,100,250	4,100,250
Reserve for exercise of Private and Additional Private Warrants	496,941	496,941
Reserve for Transaction Warrants	5,454,524	—
Reserve for exercise of SPA warrants	2,262,585	—
Reserve for convertible debt	15,766,509	—
Employee stock purchase plan	500,000	—
Reserve for convertible Series A Preferred Stock	9,436,000	—
Total	46,906,334	10,008,474

During December 2023, the Company increased the number of authorized shares under its 2022 Equity Incentive Plan to 6,000,000, of which 5,889,525 shares were still available for future grants at December 31, 2023.

NOTE 11 — PREFERRED STOCK

The Company has authorized the issuance of 1,500,000 and 1,000,000 shares of preferred stock at a par value of $0.0001 per share as of December 31, 2023 and 2022, respectively. The number of authorized shares increased from 1,000,000 shares to 1,500,000 shares by the Company's stockholders approval on December 6, 2023, through an amendment to the Amended and Restated Certificate of Incorporation.

Fiscal 2023 Redeemable Convertible Preferred Stock

The Company's Board of Directors has designated 25,000 shares of preferred stock as Series A Preferred Stock. The Series A Preferred Stock has no maturity and is not subject to any sinking fund or redemption and will remain outstanding indefinitely unless and until converted by the holder or the Company redeems or otherwise repurchases the Series A Preferred Stock.

During September 2023, the Company issued 9,526 shares of Series A Preferred Stock and the corresponding Transaction Warrants to the Investors (see Note 8 – Debt) in exchange for total cash proceeds of $9.5 million. In October 2023, the Company issued 900 shares of Series A Preferred Stock and the corresponding Transaction Warrants in exchange for total cash proceeds of $0.9 million.

During December 2023, pursuant to the terms of the Certificate of Designation of the Series A Preferred Stock, two investors of the Company, converted an aggregate of 990 Series A Preferred Stock into 990,000 shares of Common Stock. Upon conversion, the carrying value of $1.2 million of the Series A Preferred Stock was reclassified to additional paid-in capital. There was no gain or loss recognized on the transaction as the shares were converted *i*n accordance with the original terms of the Certificate of Designations for the Series A Preferred Stock. At December 31, 2023, there were 9,436 shares of Series A Preferred Stock outstanding with a liquidation preference of $14.2 million.

Dividends

Dividends on each share of Series A Preferred Stock are payable at the rate of 8% (the "Dividend Rate") of the purchase price of $1,000.00 per share (the "Stated Value"). Dividends are payable semi-annually to holders of record on March 1 and September 1 on March 15 and September 15 of each year, respectively, with the first payment date being March 15, 2024, the dividend for which will reflect the period from closing through March 15, 2024.

Dividends are payable in shares of Common Stock (a "PIK Dividend"). The number of dividend shares is equal to the Stated Value of each such share of Series A Preferred Stock multiplied by the dividend rate of 8.0% per annum and divided by $1.00, as adjusted from time to time for any stock split, stock dividend, recapitalization or otherwise, computed on the basis of a 360-day year and twelve 30-day months. Any fractional shares of a PIK Dividend will be rounded to the nearest whole share. All shares of Common Stock issued in payment of a PIK Dividend will be duly authorized, validly issued, fully paid and non-assessable. Dividends will accumulate whether or not the Company has earnings, there are funds legally available for the payment of those dividends and whether or not those dividends are declared by the Company's Board of Directors.

Conversion Features

Each share of Series A Preferred Stock is convertible at any time and in the sole discretion of the holder, into shares of Common Stock at a conversion rate of $1.00 per share (the "Conversion Rate") plus any accrued but unissued PIK Dividends, when converted, subject to certain restrictions on conversion prior to the Company obtaining stockholder approval. If the Company issues or sells Common Stock at a price below the current conversion rate of $1.00 per share, the conversion rate will be adjusted downward immediately following the dilutive issuance. The new conversion rate will be calculated based on a formula that takes into account the previous conversion rate, number of shares outstanding before and after issuance, and the consideration received by the Company in connection with the dilutive issuance. Certain types of agreements to sell Common Stock at market pricing will be evaluated on a quarterly basis or immediately prior to a Liquidation Event for purposes of determining if they collectively constitute a dilutive issuance.

The Company can initiate a mandatory conversion at any time when the resale of issued Common Stock is covered under an effective registration statement or can be sold without volume limitations under Rule 144 (or successor rule), as determined by the counsel to the Company. The Series A Preferred Stock will automatically convert into shares of Common Stock at the Conversion Rate, as follows: (i) 50% of the issued and outstanding Series A Preferred Stock will convert into shares of Common Stock if the VWAP trading price for the shares of Common Stock are trading on a national exchange is greater than $4.50 per share for twenty of any thirty consecutive trading days, and (ii) the remaining issued and outstanding Series A Preferred Stock will convert into shares of Common Stock if the VWAP trading price for the shares of Common Stock are trading on a national exchange greater than $6.00 per share for twenty of any thirty consecutive trading days.

The Company analyzed the embedded conversion options for derivative accounting consideration under ASC 815-15 "*Derivatives and Hedging*" and determined that the conversion options are equity classified.

Voting Rights

Each Series A Preferred Stockholder is entitled to the whole number of votes equal to the number of shares of Common Stock into which such holder's Series A Preferred Stock would be convertible on the record date for the vote or consent of stockholders at a conversion price of $1.04 per share of Common Stock rounded to the nearest whole share.

Liquidation Preferences and Redemption Rights

The Series A Preferred Stock has senior ranking over Common Stock of the Company, and junior to the Company's indebtedness, in each case for purposes of dividends, distributions, and payments in a liquidation event.

In the event of a liquidation event, holders of Series A Preferred Stock are entitled to receive in cash out of the assets of the Company legally available, whether from capital or from earnings available for distribution to its stockholders, before any amount shall be paid to the holders of Common Stock, an amount in cash per share of Series A Preferred Stock equal to the greater of: (i) 150% of the Stated Value and (ii) the value of the per share consideration paid to the holders of the Common Stock in the Liquidation Event as if the Series A Preferred Stock held by such holder had been converted prior to the liquidation event, subject to certain exceptions as stipulated in the Company's Certificate of Designations for the Series A Preferred Stock.

The Series A Preferred Stock are redeemable upon the occurrence of any transaction or series of related transactions pursuant to which the Company effects (i) any merger or consolidation of the Company where the Company is not the surviving entity, (ii) any sale of all or substantially all of its assets, or (iii) any reclassification of the Common Stock or any compulsory share exchange pursuant to which the Common Stock is effectively converted into or exchanged for other securities, cash or property (a "Fundamental Transaction"). In the event of a Fundamental Transaction, holders of Series A Preferred Stock are entitled to receive in cash the greatest of: (i) 150% of the Stated Value, (ii) the Stated Value of Series A Preferred Stock, plus to the extent holders of Common Stock will receive cash consideration in exchange for their Common Stock in a Fundamental Transaction, cash consideration equal to the value of any accrued but unpaid dividends, and (iii) the value of the per share consideration paid to the holders of the Common Stock in the Fundamental Transaction as if the Series A Preferred Stock held by such holder had been converted prior to the Fundamental Transaction.

As part of the Company's analysis of the classification of the Series A Redeemable Convertible Preferred Stock, the Company considered the guidance in ASC 480-10-S99-3A and in particular paragraphs 2 and 3f, which require preferred securities that are redeemable for cash or other assets to be classified outside of permanent equity if they are redeemable upon the occurrence of an event that is not solely within the control of the issuer. Due to the consideration payable upon a Fundamental Transaction and the liquidation preferences of the Series A Preferred Stock providing for payout on the Series A Preferred Stock prior to payment to the Common Stockholders, the Company cannot avail itself of the limited exception of paragraph ASC 480-10-S99-3A-3f. As a result, the Company concluded that the Series A Preferred Stock are subject to ASR 268, Presentation in Financial Statements of "Redeemable Preferred Stocks," and should be classified outside of permanent equity.

Fiscal 2022 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 $2.1 million related to these awards. The Company determined 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 13 – 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 Note 12 – Earn-Out Shares.

NOTE 12 — 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 subsequently remeasured the liability with changes in fair value recorded in the consolidated statements of operations at each reporting period.

The changes in fair value of the earnout liability for the years ended December 31, 2023 and 2022 are as follows (in thousands):

	Amount
Earnout liability, January 1, 2022	$ —
Issuance of earnout liability	22,070
Change in fair value	(9,260)
Earnout liability, December 31, 2022	12,810
Change in fair value	(12,190)
Earnout liability, December 31, 2023	$ 620

NOTE 13 — STOCK-BASED COMPENSATION

Of the Company's 2019 restricted common C shares, 600,000 vested upon consummation of the Business Combination on December 6, 2022. An additional 254,507 vested as per the vesting schedule, prior to the consummation of the Business Combination. There were no outstanding restricted common C shares as of December 31, 2023 and 2022.

During May 2023, the Company issued 20,000 shares of Common Stock to a consultant for services received. The fair value of the shares issued of $0.2 million was recognized as general and administrative expense with a corresponding credit to additional paid-in capital.

2022 Equity Incentive Plan

In 2022, the Company established the 2022 Equity Incentive Stock Plan (the "2022 Plan"), which authorizes the issuance of incentive and nonqualified stock options and RSUs for the acquisition of shares of the Company's Common Stock, as well as grants of restricted Common Stock units to employees, officers, directors, and consultants of the Company. The 2022 Plan provides that the exercise price of incentive stock options cannot be less than 100% of the fair market value of the Common Stock on the date of the award for participants who own less than 10% of the total combined voting power of stock of the Company, and not less than 110% for participants who own more than 10% of the Company's voting power. The vesting period for the option is outlined in percentage installments on the grant notice. The option can only be exercised to the extent that it is vested and exercisable. The Grantee has the right to exercise the option until it expires or is terminated, as long as it is vested and exercisable. The stock options generally expire not more than ten years from the date of grant, who own less than 10% of the total combined voting power of stock of the Company and the expiration note more than 5 years from the date of grant, who own more than 10% of the Company's voting power.

There were no awards issued under the 2022 Plan for the year ended December 31, 2022. During the year ended December 31, 2023, the Company granted 1,668,915 options to certain employees and consultants of the Company. As of December 31, 2023, there were 6,000,000 authorized shares and 5,889,525 available for future grants under the 2022 Plan.

Stock option activity for the year ended December 31, 2023, was as follows (aggregate intrinsic value in thousands):

Stock-Based Compensation	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at January 1, 2023	—	$ —		
Granted	1,668,915	4.70		
Exercised	—			
Cancelled	(106,418)	5.20		
Outstanding at December 31, 2023	1,562,497	$ 4.67	9.2 years	$ 35
Exercisable at December 31, 2023	—	—	—	—
Vested and expected to vest as of December 31, 2023	1,562,497	$ 4.67	9.2 years	$ 35

As of December 31, 2023, unamortized compensation expense related to unvested stock options was $3.2 million, which is expected to be recognized over a weighted average period of 3.11 years.

The weighted-average grant date fair value of options granted during the year ended December 31, 2023, was $2.60. The Company estimated the fair value of stock options using the Black-Scholes option pricing model. The fair value of the stock options was estimated using the following weighted average assumptions:

	December 31, 2023
Dividend yield	0.0%
Expected volatility	55.0%
Risk-free interest rate	3.6%
Expected life	6.2 years

Dividend Rate—The expected dividend rate was assumed to be zero, as the Company had not previously paid dividends on Common Stock and has no current plans to do so.

Expected Volatility—The expected volatility was derived from the historical stock volatilities of several public companies within the Company's industry that the Company considers to be comparable to the business over a period equivalent to the expected term of the stock option grants.

Risk-Free Interest Rate—The risk-free interest rate is based on the interest yield in effect at the date of grant for zero coupon U.S. Treasury notes with maturities approximately equal to the option's expected term.

Expected Term—The expected term represents the period that the Company's stock options are expected to be outstanding. The expected term of option grants that are considered to be "plain vanilla" are determined using the simplified method. The simplified method deems the term to be the average of the time-to-vesting and the contractual life of the options. For other option grants not considered to be "plain vanilla," the Company determined the expected term to be the contractual life of the options.

Forfeiture Rate—The Company recognizes forfeitures as they occur.

The Company's 2022 Plan has a "clawback policy" based on which the Company may recover from a participant any compensation received from any stock right (whether or not settled) or cause a participant to forfeit any such stock right in the event that the Company's clawback policy then in effect is triggered. The Company's clawback policy is compliant with provisions of applicable law, including the requirements set forth in Listing Rule 5608 of the corporate governance rules of the NASDAQ Stock Market.

Restricted Stock Units

During October 2023, the Company granted 736,250 Restricted Stock Units (RSUs) to certain employees under the 2022 Plan. Of these RSUs, 543,750 cliff vest on October 15, 2025 and the remainder fully vested during 2023. The Board has the discretion to accelerate the vesting of unvested Restricted Stock Units at any time, as per the terms of the Plan. The RSUs represent the right to receive Common Stock of the Company, but the participant has no right to payment until the RSUs vest. The vested RSUs will be paid in whole shares of Common Stock within 60 days of the vesting date. If the participant ceases to be a service provider, the unvested RSUs will be forfeited at no cost to the Company, and the participant will have no further rights under the award agreement.

RSU activity for the year ended December 31, 2023, was as follows:

	Number of Units	Weighted-Average Exercise Price
Unvested at January 1, 2023	—	$ —
Granted	736,250	0.86
Vested	(192,500)	0.86
Forfeited	—	—
Unvested balance at December 31, 2023	543,750	$ 0.86

The Company has recorded stock-based compensation expense for the year ended December 31, 2023, related to the grants of stock option awards to employees and nonemployees in the consolidated statements of operations as follows (in thousands):

	December 31, 2023
Cost of revenue	$ 24
Sales and marketing	128
Research and development	232
General and administrative	793
	$ 1,177

During the year ended December 31, 2023, the Company recorded stock-based compensation expense related to the vested RSUs of $0.1 million. As of December 31, 2023, unamortized compensation expense related to unvested RSUs was $0.4 million, which is expected to be recognized over a weighted average period of 1.79 years.

The Company did not recognize any tax benefits related to stock-based compensation expense during the years ended December 31, 2023 and 2022.

Share-based compensation expense for the year ended December 31, 2022, was $2.2 million relating to restricted common C shares and the issuance of Series A Redeemable Convertible Preferred Stock to certain employees (see Note 11 –Preferred Stock).

2023 Employee Stock Purchase Plan

The Company’s Board of Directors previously adopted, and the Company's stockholders approved, the Company’s 2023 Employee Stock Purchase Plan (the “2023 ESPP”).

The 2023 ESPP is a broad-based plan that provides employees of the Company and its designated affiliates with the opportunity to become stockholders through periodic payroll deductions that are applied towards the purchase of shares of the Company’s Common Stock at a discount from the then-current market price. Subject to adjustment in the case of certain capitalization events, a total of 500,000 shares of Common Stock were available for purchase at adoption of the 2023 ESPP. The first offering period under the plan commenced on June 15, 2023.There were no shares issued under the plan for the year ended December 31, 2023. As of December 31, 2023, 500,000 shares of Common Stock remained available for issuance under the 2023 ESPP.

The Company estimates the fair value of ESPP grants on their grant date using the Black-Scholes option pricing model. The estimated fair value of ESPP grants is amortized on a straight-line basis over the requisite service period of the grants. The Company reviews, and when deemed appropriate, updates the assumptions used on a periodic basis. The Company utilizes its estimated volatility in the Black-Scholes option pricing model to determine the fair value of ESPP grants. ESPP compensation expense for the year ended December 31, 2023, was de minimis.

NOTE 14 — INCOME TAXES

The loss before provision for income taxes for financial reporting purposes for the years ended December 31, 2023 and 2022, the domestic component was $24.1 million and $7.1 million, respectively. The provision for income tax for the years ended December 31, 2023 and 2022 was de minimis and consisted solely of current state income taxes.

The following table presents a reconciliation of the tax expense computed at the statutory federal rate and the tax expenses for the periods presented (in thousands):

	Years Ended December 31,	
	2023	2022
Statutory federal income tax rate	$ (5,057)	$ (1,499)
State taxes, net of federal tax benefit	(1,114)	(1,757)
Valuation allowance	8,840	8,167
Change in fair value of warrant liability	(398)	(678)
Change in fair value of debt	(799)	(2,227)
Transaction costs	—	(528)
Stock compensation	16	450
Change in fair value of earnout liability	(2,560)	(1,942)
Excess fair value of refinanced debt	466	—
Financing costs	519	—
Other permanent differences	87	14
	$ —	$ —

Deferred income taxes reflect the net tax effects of loss and credit carryforwards and temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of Company's deferred tax assets for federal and state income taxes are as follows (in thousands):

	Years Ended December 31,	
	2023	2022
Deferred tax assets		
Net operating losses	$ 25,487	$ 17,848
Reserves and accruals	699	619
Debt issuance cost amortization	703	1,184
Debt extinguishment amortization	2,345	646
Debt related warrants	851	1,408
Capitalized research and development	1,224	558
Lease liabilities	1,326	1,541
Stock based compensation	229	—
Other deferred tax assets	—	1
Gross deferred tax assets	32,864	23,805
Valuation allowance	(31,163)	(22,022)
Net deferred tax assets	$ 1,701	$ 1,783
Deferred tax liabilities		
Depreciation and amortization	(485)	(271)
Right of use assets	(1,216)	(1,512)
Total deferred tax liabilities	(1,701)	(1,783)
Net deferred tax assets (liabilities)	$ —	$ —

Realization of deferred tax assets is dependent upon future pretax earnings, the reversal of temporary differences between book and tax bases of assets and liabilities, and the enacted tax rates in effect in future periods. The Company has recorded a full valuation allowance as of December 31, 2023 and December 31, 2022. The change in the valuation allowance was an increase of $9.1 million and $8.2 million for the years ended December 31, 2023 and 2022, respectively.

As of December 31, 2023, the Company had net operating loss carryforwards for federal and state income tax purposes of approximately $99.5 million and $52.9 million, respectively. Of the $99.5 million of net operating loss carryforwards for federal purposes, $69.4 million have an unlimited carry-forward period. The remaining federal carryforwards begin to expire in 2027 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 $44.8 million 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, 2023 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, 2023.

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 statements of operations was zero for both of the years ended December 31, 2023 and 2022.

The Company files income tax returns in the US federal and various state with varying statutes of limitations. The Company is generally no longer subject to tax examinations for years prior to 2008 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. The Company does not anticipate that any potential tax adjustments will have a significant impact on our financial position or results of operations.

NOTE 15 — EMPLOYEE BENEFIT PLAN

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, 2023 and 2022 were $0.3 million and $0.1 million, respectively.

NOTE 16 — 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 (in thousands, except per share amounts):

	Years Ended December 31,	
	2023	**2022**
Numerator:		
Net loss attributable to Common Stockholders	$ (24,095)	$ (7,145)
Denominator:		
Weighted-average common shares outstanding	16,177	10,022
Net loss per share attributable to Common Stockholders, basic and diluted	$ (1.49)	$ (0.71)

** Basic and diluted weighted-average common shares outstanding for the year ended December 31, 2022, has been computed based on the historical weighted-average common shares outstanding multiplied by the exchange ratio established in the Business Combination.*

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, 2023 and 2022 because including them would have been antidilutive are as follows:

	Years Ended December 31,	
	2023	2022
Conversion of Series A Preferred Stock	9,436,000	—
Outstanding Options to purchase Common Stock	1,562,497	—
RSUs to purchase Common Stock	543,750	—
Senior and Subordinated Convertible Notes	20,080,459	3,179,410
Warrants to purchase Common Stock	11,966,611	6,512,087
Total	43,589,317	9,691,497

NOTE 17 — SUBSEQUENT EVENTS

Pursuant to the Certificate of Designations, Preferences and Rights of Series A Convertible Preferred Stock, par value $0.0001 of the Company (the "Certificate of Designations"), on March 15, 2024, the Company was obligated to pay dividends per share of Series A Preferred Stock held on March 1, 2024, payable as the number of shares of Common Stock at a rate of 8% per annum. Due to limitations under Delaware law, the Company did not declare the PIK Dividend. As a result, on March 15, 2024, the Conversion Rate (as that term is defined in the Certificate of Designations) for each outstanding share of the Series A Preferred Stock was increased to reflect the accrued and unpaid dividend. To the extent the PIK Dividend or any other dividend related to the Series A Preferred Stock is paid in the future, the Conversion Rate will be reduced accordingly.

The indentures governing the Company's Convertible Notes require compliance with certain financial covenants on a monthly and quarterly basis. As of March 1, 2024, the Company was in violation of the minimum cash covenant on the Convertible Notes. On March 25, 2024, the lenders agreed to (i) waive the minimum cash covenant for the period commencing on March 1, 2024 through and including June 30, 2024 provided that the Company's cash balance remains above $2.5 million during such period; and (ii) waive any default under the indentures resulting from any breach by the Company that may have arisen up to March 1, 2024.

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. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosure. Based on this evaluation, and in light of the weaknesses in our internal control over financial reporting described below, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were not effective as of December 31, 2023.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) and 15d-15(f) under the Exchange Act). Our Chief Executive Officer and Chief Financial Officer assessed the effectiveness of our internal control over financial reporting as of December 31, 2023. In making this assessment, our Chief Executive Officer and Chief Financial Officer used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO, in Internal Control—Integrated Framework. Based on that assessment and using the COSO criteria, our Chief Executive Officer and Chief Financial Officer have concluded that, as of December 31, 2023, our internal control over financial reporting was not effective because of the material weaknesses described below.

A material weakness is defined as "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 a company's annual or interim financial statements will not be prevented or detected on a timely basis."

As of December 31, 2023, the following material weaknesses have been identified:

Segregation of Duties and Reviews of Complex Accounting Matters: We did not design and maintain effective segregation of duties due to limited staffing in our accounting function. Specifically, we do not have sufficient resources in our accounting department, which restricts our ability to segregate roles and access to ensure effective segregation of duties. Furthermore, reviews surrounding the application of complex accounting matters were insufficient.

Journal Entries: We did not design and maintain effective monitoring controls related to manual journal entries to ensure that journal entries are not modified after approval.

Information Technology General Controls: We did not design and maintain effective information technology general controls for systems and applications that are relevant to the preparation of the consolidated financial systems. Specifically, we did not design and maintain controls around user access control to ensure proper authorization and segregation of duties that would restrict user and privileged access to the financially relevant systems and data to appropriate personnel. Additionally, we did not design and/or implement sufficient controls for program change management to certain financially relevant systems affecting our processes. As a result, automated and IT-dependent business process controls that are dependent on the effectiveness of the underlying systems and applications are also deemed ineffective.

Control Documentation: Due to staffing and system limitations, we were not able to maintain adequate formal documentation evidencing the existence and operation of our internal controls that would address all the relevant financial reporting risks of the Company.

Planned Remediation

During 2024, we intend to work to remediate the material weaknesses identified above, which is expected to include (i) the addition of accounting and financial personnel and segregating duties amongst the personnel (ii) enhancing the design and documentation of information technology general controls, (iii) the modification to our accounting processes and enhancement to our financial controls, (iv) formalizing our internal control documentation and strengthening monitoring reviews by our management; (v) implementing new applications and systems that are aligned with management's focus on creating strong internal controls and (vi) the hiring of an independent consulting or accounting firm to review and document our internal control system to ensure compliance with COSO. However, our current financial position could make it difficult for us to add the necessary resources.

We are currently working to improve and simplify our internal processes and implement enhanced controls, as discussed above, to address the material weaknesses in our internal control over financial reporting and to remedy the ineffectiveness of our disclosure controls and procedures. These material weaknesses will not be considered to be remediated until the applicable remediated controls are operating for a sufficient period of time and management has concluded, through testing, that these controls are operating effectively.

Despite the existence of these material weaknesses, we believe that the financial statements included in the period covered by this Annual Report on Form 10-K fairly present, in all material respects, our financial condition, results of operations and cash flows for the periods presented in conformity with U.S. generally accepted accounting principles.

Changes in Internal Control over Financial Reporting

Other than as described above, there have been 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 year ended December 31, 2023 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 2024 Proxy Statement, which will be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2023, and is incorporated herein by this reference.

Item 11. Executive Compensation

The information required by this Item will be included in our 2024 Proxy Statement, which will be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2023, 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 2024 Proxy Statement, which will be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2023, 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 2024 Proxy Statement, which will be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2023, 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 2024 Proxy Statement, which will be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2023, and is incorporated herein by this reference.

Part IV

Item 15. Exhibits and Financial Statement Schedules

(a) We have filed the following documents as part of this Annual Report on Form 10-K:

a. Financial Statements

i. See the Index to Consolidated Financial Statements under Part II, Item 8 of this Annual Report on Form 10-K.

b. Financial Statement Schedules

i. Schedules not listed above have been omitted because they are not required, because they are not applicable, or because the required information is otherwise included.

c. Exhibits

i. The exhibits listed below are filed as part of this Annual Report on Form 10-K or are incorporated herein by reference, in each case as indicated below.

(b)

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).
3.3	Certificate of Designations (previously filed as Exhibit 3.1 of the Company's Current Report on Form 8-K filed with the SEC on September 21, 2023).
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 (incorporated by reference to Exhibit 4.3 of the Registration Statement on Form S-1/A filed by Lakeshore with the SEC on April 22, 2021).
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).
4.5	Indenture for Senior Secured Convertible Notes due 2025, dated December 6, 2022 by and between ProSomnus, Inc., ProSomnus Holdings, Inc. and ProSomnus Sleep Technologies, as guarantors, and Wilmington Trust, National Association, as trustee and collateral agent (incorporated by reference to Exhibit 10.9 to the Company's Current Report on Form 8-K filed with the SEC on December 13, 2022).
4.6	First Supplemental Indenture, dated as of June 29, 2023, by and among ProSomnus, Inc., ProSomnus Holdings, Inc. and ProSomnus Sleep Technologies, Inc., as guarantors, and Wilmington Trust, National Association (incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K filed with the SEC on June 30, 2023).
4.7	Second Supplemental Indenture, dated as of September 20, 2023, by and among ProSomnus, Inc., ProSomnus Holdings, Inc. and ProSomnus Sleep Technologies, Inc., as guarantors, and Wilmington Trust, National Association (incorporated by reference to Exhibit 4.2 of the Company's Current Report on Form 8-K filed with the SEC on September 21, 2023).
4.8	Indenture for Subordinated Secured Convertible Notes due 2026, dated December 6, 2022 by and between ProSomnus, Inc., ProSomnus Holdings, Inc. and ProSomnus Sleep Technologies, as guarantors, and Wilmington Trust, National Association, as trustee and collateral agent (incorporated by reference to Exhibit 10.10 to the Company's Current Report on Form 8-K filed with the SEC on December 13, 2022).
4.9	First Supplemental Indenture, dated as of June 29, 2023, by and among ProSomnus, Inc., ProSomnus Holdings, Inc. and ProSomnus Sleep Technologies, Inc., as guarantors, and Wilmington Trust, National Association (incorporated by reference to Exhibit 4.2 of the Company's Current Report on Form 8-K filed on June 30, 2023).
4.10	Second Supplemental Indenture, dated as of September 20, 2023, by and among ProSomnus, Inc., ProSomnus Holdings, Inc. and ProSomnus Sleep Technologies, Inc., as guarantors, and Wilmington Trust, National Association (incorporated by reference to Exhibit 4.3 of the Company's Current Report on Form 8-K filed with the SEC on September 21, 2023).
4.11	Indenture, dated as of October 11, 2023, by and among ProSomnus, Inc., ProSomnus Holdings, Inc. and ProSomnus Sleep Technologies, Inc., as guarantors, and Wilmington Trust, National Association, as trustee and collateral agent (incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K filed with the SEC on October 12, 2023).
4.12	Form of Senior Secured Convertible Exchange Note due December 6, 2025 (incorporated by reference to Exhibit 4.2 of the Company's Current Report on Form 8-K filed with the SEC on October 12, 2023).

4.13	Indenture, dated as of October 11, 2023, by and among ProSomnus, Inc., ProSomnus Holdings, Inc. and ProSomnus Sleep Technologies, Inc., as guarantors, and Wilmington Trust, National Association, as trustee and collateral agent (incorporated by reference to Exhibit 4.3 of the Company's Current Report on Form 8-K filed with the SEC on October 12, 2023).
4.14	Form of Subordinated Secured Convertible Exchange Note due April 6, 2026 (incorporated by reference to Exhibit 4.4 of the Company's Current Report on Form 8-K filed with the SEC on September 21, 2023).
4.15	Form of Warrant (previously filed as exhibit 4.1 of Form 8-K filed by ProSomnus with the SEC on September 21, 2023)
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 Amended Equity Incentive Plan and forms of equity agreements thereunder (previously filed as Exhibit 10.2 of Form 8-K filed by ProSomnus with the SEC on December 11, 2023).
10.14	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).
10.15	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).
10.16	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).
10.17	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).
10.18	Employment Agreement with Brian Dow (incorporated by reference to Exhibit 10.1 of the Company's Current Report Form 8-K with the SEC on March 1, 2023).
10.19	Form of Securities Purchase Agreement, dated as of September 20, 2023, by and among ProSomnus, Inc. and the investors named therein (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on September 21, 2023).
10.20	Senior Security Agreement, dated as of October 11, 2023, by and among ProSomnus, Inc., the subsidiaries of ProSomnus, Inc., from time to time party thereto, and Wilmington Trust, National Association, as collateral agent (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on October 12, 2023).
10.21	Subordinated Security Agreement, dated as of October 11, 2023, by and among ProSomnus, Inc., the subsidiaries of ProSomnus, Inc., from time to time party thereto, and Wilmington Trust, National Association, as collateral agent (incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K filed with the SEC on October 12, 2023).
10.22+	Restated Employment Agreement by and between ProSomnus, Inc. and Dr. Mark Murphy, dated August 7, 2023 (previously filed as exhibit 10.1 on Form 10-Q with the SEC on August 9, 2023).
10.23	Form of Restricted Stock Unit Award (previously filed as Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on October 19, 2023).
10.24	Form of executive employment agreement (previously filed as Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on December 11, 2023).
10.25+*	2023 Employee Stock Purchase Plan.
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
24.1*	Power of Attorney (included in the signature page hereto)

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
97.1**	Clawback Policy
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.
**Furnished 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 March 27, 2024.

PROSOMNUS, INC.

By: /s/ Len Liptak
Name: Len Liptak
Chief Executive Officer
Date: March 27, 2024

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)	March 27, 2024
/s/ Brian Dow Name: Brian Dow	Chief Financial Officer and Corporate Secretary (Principal Financial Officer and Principal Accounting Officer)	March 27, 2024
/s/ Laing Rikkers Name: Laing Rikkers	Executive Chair	March 27, 2024
/s/ Leonard Hedge Name: Leonard Hedge	Director	March 27, 2024
/s/ William Johnson Name: William Johnson	Director	March 27, 2024
/s/ Jason Orchard Name: Jason Orchard	Director	March 27, 2024
/s/ Steven Pacelli Name: Steven Pacelli	Director	March 27, 2024
/s/ Heather Rider Name: Heather Rider	Director	March 27, 2024

Exhibit 4.1

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

The following information describes the capital stock of ProSomnus, Inc. ("us," "our," "we" or the "Company"), as well as certain provisions of our amended and restated certificate of incorporation (our "Certificate of Incorporation), certificate of designations, preferences and rights of our Series A Convertible Preferred Stock, par value $0.0001 (the "Certificate of Designations"), and amended and our restated bylaws (our "Bylaws"). This summary does not purport to be complete and is qualified in its entirety by the provisions of our Certificate of Incorporation and Bylaws, copies of which have been filed as exhibits to our Annual Report on Form 10-K, of which this description has also been filed as an exhibit, as well as to the applicable provisions of the Delaware General Corporation Law (the "DGCL").

General

Our authorized capital stock consists of the issuance of 151,500,000 shares, consisting of 150,000,000 shares of common stock, par value of $0.0001 per share, and 1,500,000 shares of preferred stock, par value $0.0001 per share.

Common Stock

The holders of common stock are entitled to one vote for each share held on all matters to be voted on by shareholders and do not have cumulative voting rights. There is no cumulative voting with respect to the election of directors, with the result that the holders of more than 50% of the shares of common stock voted for the election of directors can elect all of the directors. The holders of common stock are entitled to receive dividends ratably, if and when declared by the board of directors out of funds legally available therefor.

In the event of a liquidation, dissolution or winding up of our Company, our stockholders will be entitled to share ratably in all assets remaining available for distribution to them after payment of liabilities and after provision is made for each class of stock, if any, having preference over the common stock.

Holders of common stock have no conversion, preemptive or other subscription rights, and there are no sinking fund or redemption provisions applicable to the common stock. The rights, preferences and privileges of the holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

Preferred Stock

Our Certificate of Incorporation grants our board of directors the authority, without further stockholder authorization, to issue from time to time up to 1,500,000 shares of preferred stock in one or more series and to fix the terms, limitations, voting rights, relative rights and preferences and variations of each series, of which 25,000 have been authorized to our Series A Convertible Preferred Stock (as described below, the "Series A Preferred Stock").

The issuance of shares of preferred stock, or the issuance of rights to purchase such shares, could decrease the amount of earnings and assets available for distribution to the holders of common stock, could adversely affect the rights and powers, including voting rights, of the common stock and could have the effect of delaying, deterring or preventing a change of control of us or an unsolicited acquisition proposal.

Series A Preferred Stock

Each share of Series A Preferred Stock has the powers, designations, preferences and other rights as are set forth in the Certificate of Designations filed by us with the Delaware Secretary of State on September 20, 2023.

The "Stated Value" per share of Series A Preferred Stock is $1,000, subject to adjustment to preserve such value for stock splits, stock dividends, recapitalizations, reorganizations, reclassifications, combinations, reverse stock splits or other similar events relating to the Series A Preferred Stock.

The Series A Preferred Stock ranks senior to the common stock and any of our other capital stock other than Pari Passu Stock (as defined below) with respect to dividends, distributions and payments upon a Liquidation Event (as defined in the Certificate of Designations); provided, however, that the Series A Preferred Stock shall be of junior rank to any indebtedness by the Company, excluding equity securities and non-convertible preferred stock.

In the event of a Liquidation Event, holders of Series A Preferred Stock (each, a "Holder" and, collectively, the "Holders") shall be entitled to receive in cash out of our assets legally available therefor (the "Liquidation Funds") upon such Liquidation Event, but before any amount shall be paid to the holders of Junior Stock (as defined in the Certificate of Designations), an amount in cash per share of Series A Preferred Stock equal to the greater of: (i) 150% of the Stated Value and (ii) the value of the per share consideration paid to the holders of the common stock in the Liquidation Event as if the Series A Preferred Stock held by such Holder had been converted prior to the Liquidation Event; provided that, if the Liquidation Funds are insufficient to pay the full amount due to the Holders and holders of shares of other classes or series of preferred stock of the Company, if any, that are of equal rank with the Series A Preferred Stock as to payments of Liquidation Funds (such stock being referred to hereinafter collectively as "Pari Passu Stock"), if any, then the Holders and the holders of any such Pari Passu Stock shall share ratably in any distribution of the Liquidation Funds in proportion to the respective amounts that would otherwise be payable in respect of the shares held by them upon such distribution if all amounts payable on or with respect to the shares of Series A Preferred Stock and Pari Passu Stock were paid in full. In addition, to the extent any Liquidation Funds remain following payment of the liquidation preference on the Series A Preferred Stock and any other payments that rank senior to payments on the common stock, each Holder shall be entitled to its pro rata portion of the remaining Liquidation Funds payable to the holders of the common stock in respect of any accrued but unpaid dividends on the Series A Preferred Stock as if any such accrued but unpaid dividends had been paid out in common stock immediately prior to the Liquidation Event.

From and after March 15, 2024 (the "Initial Dividend Date"), we shall pay the following dividends semi-annually on March 15 and September 15 of each year (or, if such day is not a business day, on the first business day following such date) to the Holders of record as they appear on our books on March 1 and September 1, respectively (even if such day is not a business day) (the "Dividend Record Date"): dividends per share of Series A Preferred Stock held on the applicable Dividend Record Date in arrears for the prior six-month period (except for the dividend to be paid on the Initial Dividend Date, which shall be paid in arrears for the period from September 20, 2023 through the Initial Dividend Date), payable as the number of shares of common stock (collectively, the "PIK Shares") equal to the Stated Value of each such share of Series A Preferred Stock multiplied by the dividend rate of 8.0% per annum and divided by $1.00, computed on the basis of a 360-day year and twelve 30-day months.

Each Holder shall have the right, at such Holder's option, subject to the conversion procedures and the limitations on conversion set forth of the Certificate of Designations, to convert any or all of its shares of Series A Preferred Stock at any time into the number of fully paid, validly issued and nonassessable shares of common stock equal to the sum of (i) the quotient of the Stated Value of the shares of Series A Preferred Stock to be converted divided by the Conversion Rate (as defined below) and (ii) any PIK Shares accrued, but not yet issued with respect to such shares of Series A Preferred Stock being converted (the "Conversion Price"). No fractional shares of common stock are to be issued upon the conversion of any Series A Preferred Stock, but rather the number of shares of common stock to be issued shall be rounded up to the nearest whole number. The "Conversion Rate" shall initially be $1.00 and shall be subject to customary adjustments for stock dividends, stock splits, reclassifications and the like, and subject to price-based adjustment in the event of certain issuances of common stock, or securities convertible, exercisable or exchangeable for common stock, at a price below the then-applicable Conversion Price.

Subject to certain conditions, the Series A Preferred Stock will automatically convert into shares of common stock as follows: (i) 50% of the issued and outstanding Series A Preferred Stock held by each Holder will, subject to the conversion procedures set forth in the Certificate of Designations, automatically convert into shares of common stock if, at any time after the applicable issuance date, the VWAP (as defined in the Certificate of Designations) per share of common stock is greater than $4.50 per share for each of at least twenty (20) trading days in any period of thirty (30) consecutive trading days (such thirty (30) consecutive trading day period, the "Trading Period") and (ii) the remaining issued and outstanding Series A Preferred Stock will convert into shares of common stock if the VWAP per share of common stock is greater than $6.00 per share for each of at least twenty (20) trading day in any Trading Period.

Upon the occurrence of any transaction or series of related transactions pursuant to which we effect (i) any merger or consolidation of the Company where the Company is not the surviving entity, (ii) any sale of all or substantially all of our assets, or (iii) any reclassification of the common stock or any compulsory share exchange pursuant to which the common stock is effectively converted into or exchanged for other securities, cash or property (each a "Fundamental Transaction"), we shall purchase from each Holder, out of funds legally available therefor, all shares of Series A Preferred Stock held by such Holder (a "Fundamental Transaction Repurchase") for a purchase price per each such share of Series A Preferred Stock, payable in cash, equal to the greatest of (i) 150% of the Stated Value of such share of Series A Preferred Stock, (ii) the Stated Value of such share of Series A Preferred Stock, plus, to the extent holders of the common stock will receive cash consideration in exchange for their shares of common stock in any Fundamental Transaction, cash consideration equal to the value of any accrued but unpaid dividends, and (iii) the value of the per share consideration paid to the holders of the common stock in the Fundamental Transaction as if the Series A Preferred Stock held by such Holder had been converted prior to the Fundamental Transaction and accrued and unpaid dividends had been issued on the date of the Fundamental Transaction Repurchase. To the extent holders of the common stock will receive shares of common stock or capital stock of any successor entity in any Fundamental Transaction, we shall, as applicable, issue common stock or use commercially reasonable efforts to cause any successor entity to issue securities in the successor entity of equivalent value to the value of any accrued but unpaid dividends less any cash consideration paid in respect of accrued but unpaid dividends.

Each Holder shall be entitled to the whole number of votes equal to the number of shares of common stock into which such Holder's Series A Preferred Stock would be convertible on the record date for the vote or consent of stockholders at a conversion price of $1.04

per share of common stock rounded to the nearest whole share (subject to the limitations on conversion set forth in the Certificate of Designations), and shall otherwise have voting rights and powers equal to the voting rights and powers of the common stock to the fullest extent permitted by applicable law, including, for the avoidance of doubt, with respect to the election of our directors.

At any time when shares of Series A Preferred Stock are outstanding, certain matters will require the approval of the majority of the outstanding Series A Preferred Stock, voting as a separate class, including (i) amending, altering or changing the powers, privileges or preferences of the Series A Preferred Stock, (ii) amending, altering or repealing any provision of our Certificate of Incorporation, the Certificate of Designations or our Bylaws in a manner that adversely affects the powers, preferences or rights of the Series A Preferred Stock, (iii) (a) reclassifying, altering or amending any existing security of ours that is pari passu with or junior to the Series A Preferred Stock, if such reclassification, alteration or amendment would render such other security senior to or pari passu with, respectively, the Series A Preferred Stock or (b) reclassifying, altering or amending any existing security of ours that is pari passu with or junior to the Series A Preferred Stock, if such reclassification, alteration or amendment would render such other security senior to or pari passu with, respectively, the Series A Preferred Stock, or (iv) purchasing or redeeming (or permitting any subsidiary to purchase or redeem) or paying or declaring any dividend or making any distribution on any shares of our capital stock while any dividend in respect of the Series A Preferred Stock is unpaid and accrued.

Certain Anti-Takeover Provisions of Delaware Law and Our Charter

We have certain anti-takeover provisions in place as follows:

Staggered board of directors

Our board of directors is divided into three classes with only one class of directors being elected in each year and each class serving a three-year term. As a result, in most circumstances, a person can gain control of our board of directors only by successfully engaging in a proxy contest at two or more annual meetings.

Directors may be removed only for cause and only by the affirmative vote of at least 75% of the total voting power of all the then outstanding shares of our stock entitled to vote generally in the election of directors, voting together as a single class (other than those directors elected by the holders of any series of Preferred Stock, who shall be removed pursuant to the terms of such Preferred Stock).

Authorized but unissued shares

Our authorized but unissued common stock and preferred stock will be available for future issuances without stockholder approval and could be utilized for a variety of corporate purposes, including future offerings to raise additional capital, acquisitions and employee benefit plans. The existence of authorized but unissued and unreserved common stock and preferred stock could render more difficult or discourage an attempt to obtain control of our Company by means of a proxy contest, tender offer, merger or otherwise.

Appointment of directors

Our Certificate of Incorporation provides that newly created directorships (including those created by the board) or any vacancy on the board of directors may be filled by a majority vote of the remaining directors then in office, even if less than a quorum, or by a sole remaining director. The exercise of this authority may prevent stockholders from being able to fill vacancies on our board of directors.

Special meeting of stockholders

Our Bylaws provide that special meetings of stockholders may be called only at the direction of our board of directors. The existence of this provision could delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors.

Advance notice requirements for stockholder proposals and director nominations

Our Bylaws provide that stockholders of record seeking to bring business before our special meeting of stockholders, or to nominate candidates for election as directors at our special meeting of stockholders, must provide timely notice of their intent in writing. To be timely, a stockholder's notice will need to be received by the secretary at our principal executive offices not later than the 60th day nor earlier than 90th day prior to the meeting. Pursuant to Rule 14a-8 of the Exchange Act, proposals seeking inclusion in our annual proxy statement must comply with the notice periods contained therein. Our Bylaws also specify certain requirements as to the form and content of a stockholders' meeting. These provisions may preclude our stockholders from bringing matters before a meeting of stockholders or from making nominations for directors at a meeting of stockholders.

Stockholder action by written consent

Our Certificate of Incorporation and Bylaws provide that any action required or permitted to be a taken by stockholders must be taken at a duly called annual or special meeting of stockholders and may not be effected by written consent.

Supermajority voting requirements

Our Certificate of Incorporation requires 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 Certificate of Incorporation, which may inhibit the ability of an acquiror to effect such amendments to facilitate an unsolicited takeover attempt.

Exclusive forum selection

Our Certificate of Incorporation requires that unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, in the event that the Chancery Court does not have subject matter jurisdiction, any state court located within the State of Delaware or, if and only if all such state courts lack subject matter jurisdiction, the federal district court for the District of Delaware) shall, to the fullest extent permitted by law, be the sole and exclusive forum for (i) any derivative action or proceeding brought on behalf of us, (ii) any action asserting a claim of breach of a fiduciary duty owed by any current or former director, officer, or other employee of us to us or our stockholders, (iii) any action asserting a claim against us arising pursuant to any provision of the DGCL or our Certificate of Incorporation or Bylaws (as either may be amended from time to time), (iv) any action or proceeding to interpret, apply, enforce or determine the validity of our Certificate of Incorporation or Bylaws (including any right, obligation, or remedy thereunder), (v) any action or proceeding as to which the DGCL confers jurisdiction to the Court of Chancery of the State of Delaware or (vi) any action asserting a claim against us governed by the internal affairs doctrine against us or any director, officer, or other employee. 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. To the fullest extent permitted by law, claims made under the Securities Act must be brought in federal district court. Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder.

The enforceability of similar choice of forum provisions in other companies' organizational documents has been challenged in legal proceedings, and it is possible that, in connection with claims arising under federal securities laws, a court could find the choice of forum provisions contained in our Certificate of Incorporation to be inapplicable or unenforceable. If that were the case, because stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder, it would allow stockholders to bring claims for breach of these provisions in any appropriate forum.

Although we believe this provision benefits it by providing increased consistency in the application of Delaware law in the types of lawsuits to which it applies, the provision may have the effect of discouraging lawsuits against our directors and officers.

Section 203 of the Delaware General Corporation Law

We are governed by the provisions of Section 203 of the DGCL. In general, Section 203 prohibits a public Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date of the transaction in which the person became an interested stockholder, unless:

- the business combination or transaction which resulted in the stockholder becoming an interested stockholder was approved by the board of directors prior to the time that the stockholder became an interested stockholder;
- upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding shares owned by directors who are also officers of the corporation and shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- at or subsequent to the time the stockholder became an interested stockholder, the business combination was approved by the board of directors and authorized at an annual or special meeting of the stockholders, and not by written consent, by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

In general, Section 203 defines a "business combination" to include mergers, asset sales, and other transactions resulting in financial benefit to a stockholder and an "interested stockholder" as a person who, together with affiliates and associates, owns, or within three years did own, 15% or more of the corporation's outstanding voting stock. These provisions may have the effect of delaying, deferring or preventing changes in control of our company.

Limitation on Liability and Indemnification of Directors and Officers

The DGCL authorizes corporations to limit or eliminate, subject to certain conditions, the personal liability of directors to corporations and their stockholders for monetary damages for breach of their fiduciary duties. Our Certificate of Incorporation limits the liability of our directors to the fullest extent permitted by Delaware law.

We have purchased and intend to maintain director and officer liability insurance to cover liabilities our directors and officers may incur in connection with their services to the combined company, including matters arising under the Securities Act. Our Certificate of Incorporation and Bylaws also provide that we will indemnify our directors and officers to the fullest extent permitted by Delaware law. Our Bylaws further provide that we will indemnify any other person whom we have the power to indemnify under Delaware law. In addition, we have entered or will enter into customary indemnification agreements with each of our officers and directors.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, executive officers or persons controlling the combined company, we have been informed that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

Warrants

Public Warrants

We have outstanding certain warrants, each whole warrant exercisable for one share of common stock at an exercise price of $11.50 per share, that were issued in connection with Lakeshore Acquisition I Corp's initial public offering (the "Public Warrants"). Each Public Warrant entitles the holder thereof the purchase one share of common stock at a price of $11.50 per whole share. The Public Warrants became exercisable on December 11, 2022, 30 days following the completion of the Business Combination. However, except as set forth below, no Public Warrants will be exercisable for cash unless we have an effective and current registration statement covering the shares of common stock issuable upon exercise of the Public Warrants and a current prospectus relating to such shares. Notwithstanding the foregoing, if an exemption from registration is not available, holders will not be able to exercise their Public Warrants on a cashless basis. The Public Warrants will expire on November 11, 2027 at 5:00 p.m., Eastern Standard Time.

We may redeem the outstanding Public Warrants, in whole and not in part, at a price of $0.01 per warrant:

- at any time while the Public Warrants are exercisable,
- upon a minimum of 30 days' prior written notice of redemption,
- if, and only if, the last sales price of common stock equals or exceeds $18.00 per share for any 20 trading days within a 30-trading day period ending three business days before we send the notice of redemption, and
- if, and only if, there is a current registration statement in effect with respect to the common stock underlying the Public Warrants at the time of redemption and for the entire 30-day trading period referred to above and continuing each day thereafter until the date of redemption.

If the foregoing conditions are satisfied and we issue a notice of redemption, each warrant holder can exercise his, her or its Public Warrant prior to the scheduled redemption date. However, the price of the common stock may fall below the $18.00 trigger price as well as the $11.50 warrant exercise price per whole share after the redemption notice is issued and not limit our ability to complete the redemption.

If we call the Public Warrants for redemption as described above, our management will have the option to require all warrant holders that wish to exercise Public Warrants to do so on a "cashless basis." In such event, each warrant holder would pay the exercise price by surrendering the whole Public Warrant for that number of common stock equal to the quotient obtained by dividing (x) the product of the number of common stock underlying the Public Warrants, multiplied by the difference between the exercise price of the Public Warrants and the "fair market value" (as defined below) by (y) the fair market value. The "fair market value" shall mean the average reported last sale price of the common stock for the 20 trading days ending on the third trading day prior to the date on which the notice of redemption is sent to the warrant holders. Whether we will exercise our option to require all warrant holders to exercise their Public Warrants on a "cashless basis" will depend on a variety of factors including the price of the common stock at the time the Public Warrants are called for redemption, our cash needs at such time and concerns regarding dilutive share issuances.

The Public Warrants were issued under a warrant agreement between Continental Stock Transfer & Trust Company, as warrant agent, and us (the "Public Warrant Agreement"). The Public Warrant Agreement provides that the terms of the Public Warrants may be amended without the consent of any holder to cure any ambiguity or correct any defective provision, but requires the approval, by written consent or vote, of the holders of a majority of the then outstanding Public Warrants in order to make any change that adversely affects the interests of the registered holders.

The exercise price and number of shares of common stock issuable on exercise of the Public Warrants may be adjusted in certain circumstances including in the event of a share capitalizations, extraordinary dividend or our recapitalization, reorganization, merger or

consolidation. However, the Public Warrants will not be adjusted for issuances of common stock at a price below their respective exercise prices.

The Public Warrants may be exercised upon surrender of the warrant certificate on or prior to the expiration date at the offices of the warrant agent, with the exercise form on the reverse side of the warrant certificate completed and executed as indicated, accompanied by full payment of the exercise price, by certified or official bank check payable to us, for the number of Public Warrants being exercised. The warrant holders do not have the rights or privileges of holders of common stock and any voting rights until they exercise their Public Warrants and receive common stock. After the issuance of common stock upon exercise of the Public Warrants, each holder will be entitled to one vote for each share held of record on all matters to be voted on by stockholders.

Except as described above, no Public Warrants will be exercisable and we will not be obligated to issue common stock unless at the time a holder seeks to exercise such warrant, a prospectus relating to the shares of common stock issuable upon exercise of the Public Warrants is current and the shares of common stock have been registered or qualified or deemed to be exempt under the securities laws of the state of residence of the holder of the Public Warrants. Under the terms of the Public Warrant Agreement, we have agreed to use our best efforts to meet these conditions and to maintain a current prospectus relating to the common stock issuable upon exercise of the Public Warrants until the expiration of the Public Warrants. However, we cannot assure you that we will be able to do so and, if we do not maintain a current prospectus relating to the common stock issuable upon exercise of the Public Warrants, holders will be unable to exercise their Public Warrants and we will not be required to settle any such warrant exercise. If the prospectus relating to the common stock issuable upon the exercise of the Public Warrants is not current or if the common stock is not qualified or exempt from qualification in the jurisdictions in which the holders of the Public Warrants reside, we will not be required to net cash settle or cash settle the warrant exercise, the Public Warrants may have no value, the market for the Public Warrants may be limited and the Public Warrants may expire worthless.

Public Warrant holders may elect to be subject to a restriction on the exercise of their Public Warrants such that an electing warrant holder (and his, her or its affiliates) would not be able to exercise their Public Warrants to the extent that, after giving effect to such exercise, such holder (and his, her or its affiliates) would beneficially own in excess of 9.8% of the common stock issued and outstanding.

No fractional shares will be issued upon exercise of the Public Warrants. If, upon exercise of the Public Warrants, a holder would be entitled to receive a fractional interest in a share (as a result of a subsequent share capitalizations payable in shares of common stock, or by a split of the common stock or other similar event), we will, upon exercise, round down to the nearest whole number the number of shares of common stock to be issued to the warrant holder.

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM'S CONSENT

We consent to the incorporation by reference in the Registration Statement of ProSomnus, Inc. on Form S-8 (No. 333-270284 and 333-272618) and Form S-3 (No. 333-275241 and 333-269156) of our report dated March 27, 2024, which includes an explanatory paragraph as to the Company's ability to continue as a going concern, with respect to our audits of the consolidated financial statements of ProSomnus, Inc. as of December 31, 2023 and 2022 and for the years then ended, which report is included in this Annual Report on Form 10-K of ProSomnus, Inc. for the year ended December 31, 2023.

/s/ Marcum LLP

Marcum LLP

Portland, Maine

March 27, 2024

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO SECURITIES EXCHANGE ACT RULES 13a-14(a) and 15d-14(a), AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Len Liptak, Chief Executive Officer, certify that:

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

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

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

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

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

   b) [Paragraph intentionally omitted in accordance with SEC Release Nos. 34-47986 and 34-54942];

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

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

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

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

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

Date: March 27, 2024

By: /s/ Len Liptak
Len Liptak
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO SECURITIES EXCHANGE ACT RULES 13a-14(a) and 15d-14(a), AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Brian Dow, Chief Financial Officer, certify that:

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

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

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

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

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

   b) [Paragraph intentionally omitted in accordance with SEC Release Nos. 34-47986 and 34-54942];

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

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

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

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

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

Date: March 27, 2024

By: /s/ Brian Dow
Brian Dow
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
AND CHIEF FINANCIAL OFFICER PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of ProSomnus, Inc. (the "Registrant") on Form 10-K for the annual period ended December 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Len Liptak., Chief Executive Officer of the Company, and Brian Dow, Chief Financial Officer, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to their respective knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

Date: March 27, 2024

/s/ Len Liptak
Len Liptak
Chief Executive Officer
(Principal Executive Officer)

Date: March 27, 2024

/s/ Brian Dow
Brian Dow
Chief Financial Officer
(Principal Financial and Accounting Officer)

This certification is made solely for the purposes of 18 U.S.C. Section 1350, subject to the knowledge standard contained therein, and not for any other purpose. A signed original of this written statement required by Section 906 has been provided to the Registrant and will be retained by the Registrant and furnished to the United States Securities and Exchange Commission or its staff upon request.

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933 or the Securities Exchange Act of 1934 (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.

ProSomnus, Inc.

COMPENSATION RECOVERY POLICY

As adopted on [_], 2023

ProSomnus, Inc. (the "**Company**") is committed to strong corporate governance. As part of this commitment, the Compensation Committee (the "**Committee**") of the Board of Directors (the "**Board**") has adopted this clawback policy called the Compensation Recovery Policy (the "**Policy**"). The Policy is intended to further the Company's pay-for-performance philosophy and to comply with applicable laws by providing for the reasonably prompt recovery of certain executive compensation received by Covered Executives in the event of an Accounting Restatement. The application of the Policy to Covered Executives is not discretionary, except to the limited extent provided below, and applies without regard to whether a Covered Executive was at fault. Capitalized terms used in the Policy are defined below, and the definitions have substantive impact on its application so reviewing them carefully is important to your understanding.

The Policy is intended to comply with, and will be interpreted in a manner consistent with, Section 10D of the Securities Exchange Act of 1934 (the "**Exchange Act**"), with Exchange Act Rule 10D-1 and with the listing standards of the national securities exchange (the "**Exchange**") on which the securities of the Company are listed, including any official interpretative guidance.

Persons Covered by the Policy

The Policy is binding and enforceable against all "**Covered Executives.**" A Covered Executive is each individual who is or was ever designated as an "officer" by the Board in accordance with Exchange Act Rule 16a-1(f) (a "**Section 16 Officer**"). The Committee may (but is not obligated to) request or require a Covered Executive to sign and return to the Company an acknowledgement that such Covered Executive will be bound by the terms and comply with the Policy.

Administration of the Policy

The Committee has full delegated authority to administer the Policy. The Committee is authorized to interpret and construe the Policy and to make all determinations necessary, appropriate, or advisable for the administration of the Policy. In addition, if determined in the discretion of the Board, the Policy may be administered by the independent members of the Board or another committee of the Board made up of independent members of the Board, in which case all references to the Committee will be deemed to refer to the independent members of the Board or the other Board committee. All determinations of the Committee will be final and binding and will be given the maximum deference permitted by law.

Accounting Restatements Requiring Application of the Policy

If the Company is required to prepare an accounting restatement due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the

previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period (an "**Accounting Restatement**"), then the Committee must determine the Excess Compensation, if any, that must be recovered.

Compensation Covered by the Policy

The Policy applies to all **Incentive-Based Compensation** (certain terms used in this Section are defined below) that is **Received** on or after October 2, 2023, while the Company has a class of securities listed on a national securities exchange, and during the **Covered Period** by a person who was a Covered Executive during the Covered Period and during the performance period for the Incentive-Based Compensation. Such Incentive-Based Compensation is considered "**Clawback Eligible Incentive-Based Compensation**"). The Clawback Eligible Incentive-Based Compensation that must be recovered is the amount of Clawback Eligible Incentive-Based Compensation that exceeds the amount of Clawback Eligible Incentive-Based Compensation that otherwise would have been Received had such Clawback Eligible Incentive-Based Compensation been determined based on the restated amounts (such compensation, as computed without regard to any taxes paid, the "Excess Compensation," is referred to in the listings standards as "erroneously awarded compensation").

To determine the amount of Excess Compensation for Incentive-Based Compensation based on stock price or total shareholder return, where it is not subject to mathematical recalculation directly from the information in an Accounting Restatement, the amount must be based on a reasonable estimate of the effect of the Accounting Restatement on the stock price or total shareholder return upon which the Incentive-Based Compensation was received and the Company must maintain documentation of the determination of that reasonable estimate and provide that documentation to the Exchange.

"Accounting Restatement" means an accounting restatement due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements.

"**Incentive-Based Compensation**" means any compensation that is granted, earned, or vested based wholly or in part upon the attainment of a Financial Reporting Measure. For the avoidance of doubt, no compensation that is potentially subject to recovery under the Policy will be earned until the Company's right to recover under the Policy has lapsed.

The following items of compensation are not Incentive-Based Compensation under the Policy:

- Salaries;
- Bonuses paid solely at the discretion of the Committee or Board;
- Non-equity incentive plan awards earned solely upon satisfying one or more strategic measures or operational measures;
- Equity awards for which the grant is not contingent upon achieving any Financial Reporting Measure performance goal and vesting is contingent solely upon completion of a specified employment period; and
- Amounts paid pursuant to a severance agreement and related release.

"**Financial Reporting Measures**" are measures that are determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measures that are derived wholly or in part from such measures. Stock price and total shareholder return are also Financial Reporting Measures. A Financial Reporting Measure need not be presented within the financial statements or included in a filing with the Securities and Exchange Commission.

Incentive-Based Compensation is "**Received**" under the Policy in the Company's fiscal period during which the Financial Reporting Measure specified in the Incentive-Based Compensation award is attained, even if the payment, vesting, settlement or grant of the Incentive-Based Compensation occurs after the end of that period.

"**Covered Period**" means the three completed fiscal years immediately preceding the Accounting Restatement Determination Date. In addition, Covered Period can include certain transition periods resulting from a change in the Company's fiscal year.

"**Accounting Restatement Determination Date**" means the earlier of: (i) the date the Audit Committee of the Board concludes, or reasonably should have concluded, that the Company is required to prepare an Accounting Restatement; or (ii) the date a court, regulator, or other legally authorized body of competent jurisdiction directs the Company to prepare an Accounting Restatement.

Repayment of Excess Compensation

The Company must recover Excess Compensation reasonably promptly and Covered Executives are required to repay Excess Compensation to the Company. Subject to applicable law, the Company may recover Excess Compensation by requiring the Covered Executive to repay such amount to the Company by direct payment to the Company or such other means or combination of means as the Committee determines to be appropriate (these determinations do not need to be identical as to each Covered Executive). These means may include:

(a) requiring reimbursement of cash Incentive-Based Compensation previously paid;

(b) seeking recovery of any gain realized on the vesting, exercise, settlement, sale, transfer, or other disposition of any incentive-based awards, without regard to whether such awards are Incentive-Based Compensation or vest based on the achievement of performance goals;

(c) offsetting the amount to be recovered from any unpaid or future compensation to be paid by the Company or any affiliate of the Company to the Covered Executive;

(d) cancelling outstanding vested or unvested equity awards; and/or

(e) taking any other remedial and recovery action permitted by law, as determined by the Committee.

The repayment of Excess Compensation must be made by a Covered Executive notwithstanding any Covered Executive's belief (whether or not legitimate) that the Excess Compensation had been previously earned under applicable law and therefore is not subject to clawback.

In addition to its rights to recovery under the Policy, the Company or any affiliate of the Company may take any legal actions it determines appropriate to enforce a Covered Executive's obligations to the Company or to discipline a Covered Executive. Failure of a Covered Executive to comply with their obligations under the Policy may result in (without limitation) termination of that Covered Executive's employment, institution of civil proceedings, reporting of misconduct to appropriate governmental authorities, reduction of future compensation opportunities or change in role. The decision to take any actions described in the preceding sentence will not be subject to the approval of the Committee and can be made by the Board, any committee of the Board, or any duly authorized officer of the Company or of any applicable affiliate of the Company. For avoidance of doubt, any decisions of the Company or the Covered Executive's employer to discipline a Covered Executive or terminate the employment of a Covered Executive are independent of determinations under this Policy. For example, if a Covered Executive was involved in activities that led to an Accounting Restatement, the Company's decision as to whether to not to terminate such Covered Executive's employment would be made under its employment

arrangements with such Covered Executive and the requirement to apply this no-fault and non-discretionary clawback policy will not be determinative of whether any such termination is for cause, although failure to comply with the Policy might be something that could result in a termination for cause depending on the terms of such arrangements.

Limited Exceptions to the Policy

The Company must recover the Excess Compensation in accordance with the Policy except to the limited extent that any of the conditions set forth below is met, and the Committee determines that recovery of the Excess Compensation would be impracticable:

(a) The direct expense paid to a third party to assist in enforcing the Policy would exceed the amount to be recovered. Before reaching this conclusion, the Company must make a reasonable attempt to recover such Excess Compensation, document such reasonable attempt(s) to recover, and provide that documentation to the Exchange; or

(b) Recovery would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company, to fail to meet the legal requirements as such.

Other Important Information in the Policy

The Policy is in addition to the requirements of Section 304 of the Sarbanes-Oxley Act of 2002 that are applicable to the Company's Chief Executive Officer and Chief Financial Officer, as well as any other applicable laws, regulatory requirements, rules, or pursuant to the terms of any existing Company policy or agreement providing for the recovery of compensation.

Notwithstanding the terms of any of the Company's organizational documents (including, but not limited to, the Company's bylaws), any corporate policy or any contract (including, but not limited to, any indemnification agreement), neither the Company nor any affiliate of the Company will indemnify or provide advancement for any Covered Executive against any loss of Excess Compensation. Neither the Company nor any affiliate of the Company will pay for or reimburse insurance premiums for an insurance policy that covers potential recovery obligations. In the event that the Company is required to recover Excess Compensation pursuant to the Policy from a Covered Executive who is no longer an employee, the Company will be entitled to seek recovery in order to comply with applicable law, regardless of the terms of any release of claims or separation agreement that individual may have signed.

The Committee or Board may review and modify the Policy from time to time.

If any provision of the Policy or the application of any such provision to any Covered Executive is adjudicated to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability will not affect any other provisions of the Policy or the application of such provision to another Covered Executive, and the invalid, illegal or unenforceable provisions will be deemed amended to the minimum extent necessary to render any such provision or application enforceable.

The Policy will terminate and no longer be enforceable when the Company ceases to be listed issuer within the meaning of Section 10D of the Exchange Act.

ACKNOWLEDGEMENT

- I acknowledge that I have received and read the Compensation Recovery Policy (the "**Policy**") of ProSomnus, Inc. (the "**Company**").

- I understand and acknowledge that the Policy applies to me, and all of my beneficiaries, heirs, executors, administrators or other legal representatives and that the Company's right to recovery in order to comply with applicable law will apply, regardless of the terms of any release of claims or separation agreement I have signed or will sign in the future.

- I agree to be bound by and to comply with the Policy and understand that determinations of the Committee (as such term is used in the Policy) will be final and binding and will be given the maximum deference permitted by law.

- I understand and agree that my current indemnification rights, whether in an individual agreement or the Company's organizational documents, exclude the right to be indemnified for amounts required to be recovered under the Policy.

- I understand that my failure to comply in all respects with the Policy is a basis for termination of my employment with the Company and any affiliate of the Company as well as any other appropriate discipline.

- I understand that neither the Policy, nor the application of the Policy to me, gives rise to a resignation for good reason (or similar concept) by me under any applicable employment agreement or arrangement.

- I acknowledge that if I have questions concerning the meaning or application of the Policy, it is my responsibility to seek guidance from [the Compliance Officer, Human Resources or my own personal advisers].

- I acknowledge that neither this Acknowledgement nor the Policy is meant to constitute an employment contract.

Please review, sign and return this form to [Human Resources].

Covered Executive

_____
(*print name*)

_____
(*signature*)

_____
(date)